

# 2024 Traceability Webinar Series

## Master Data – GTINs & GLN Overview & Update

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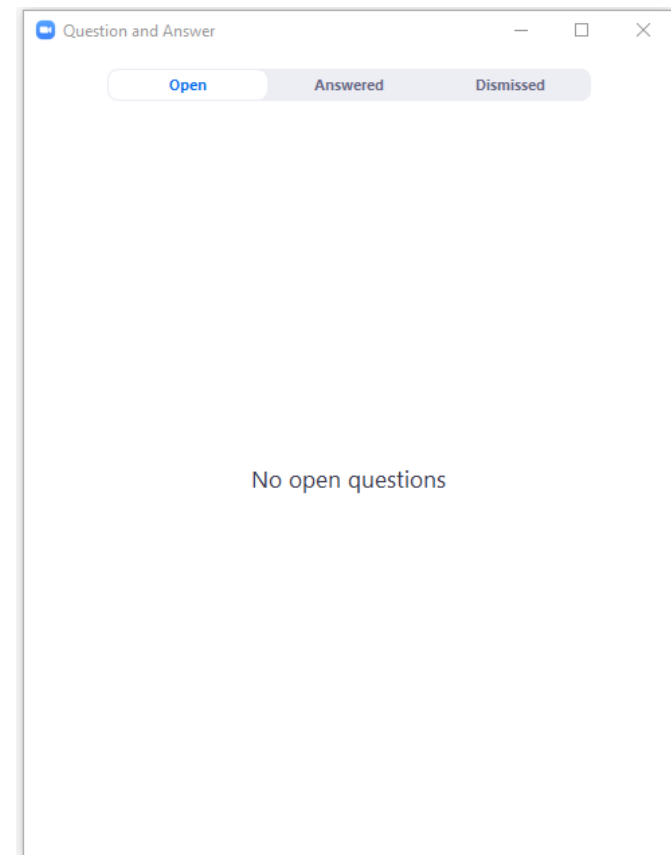
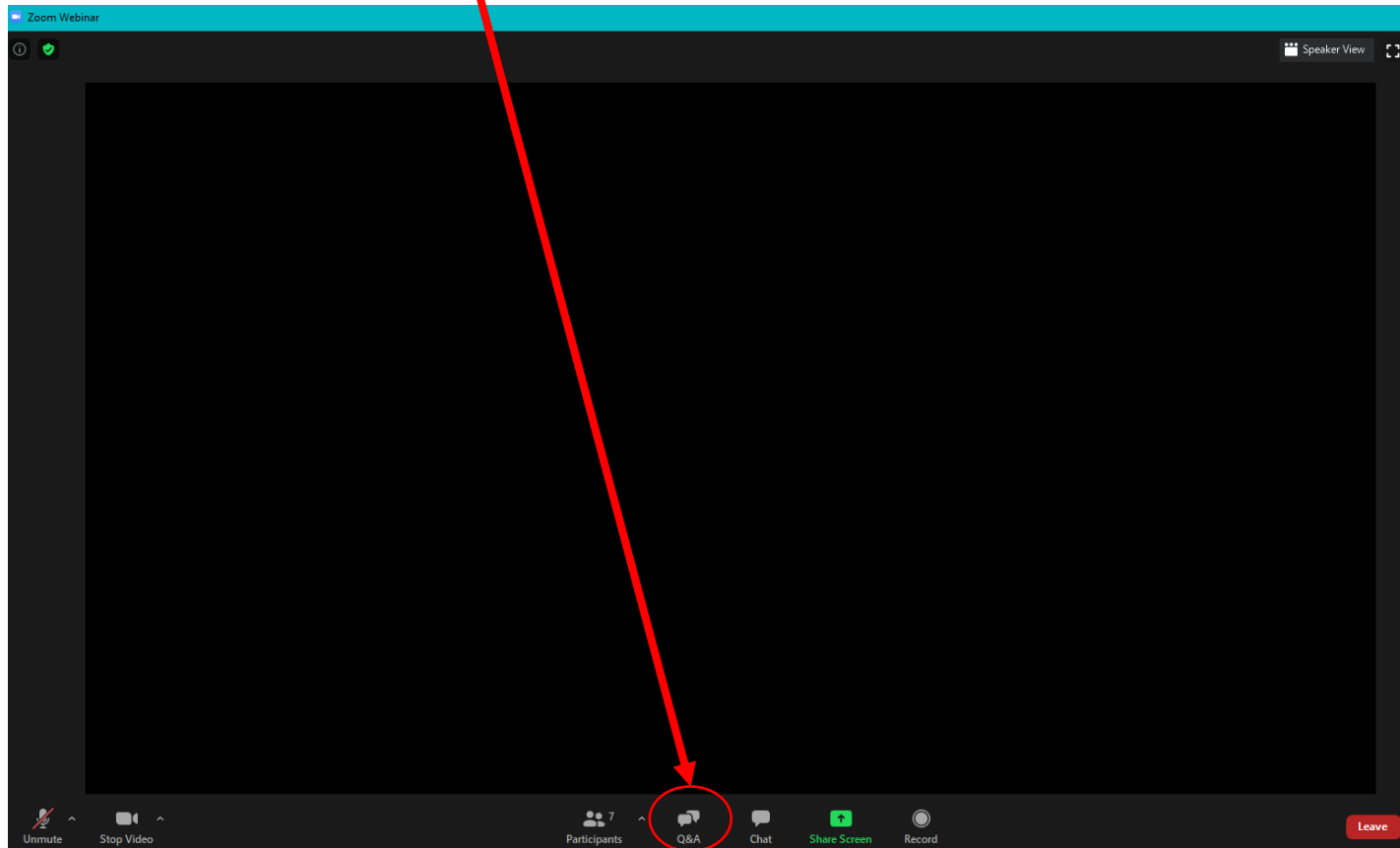
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- All participant lines are muted.
- Today's presentation and recording will be available by ***Wednesday, July 3<sup>rd</sup>***.

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# Questions & Answers

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# Panel

Ameer Ali, Sr. Director, Manufacturer Operations, Cencora, Inc.

Kevin Capatch, Director, Process Engineering, Geisinger Health System

Scott Mooney, Vice President Distribution Operations, Traceability,  
McKesson Corporation

Tracy Nasarenko, Vice President of Community Engagement,  
Healthcare, GS1 US

April Sese, DSCSA Lead, Digital Identification & Traceability, Johnson &  
Johnson Supply Chain

Moderator: Tim Stearns, Senior Director, Industry Relations, Healthcare  
Distribution Alliance



The Global Language of Business

Healthcare

# Master Data – GTINs & GLN Overview & Update

HDA Traceability Webinar

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Tracy Nasarenko  
June 27, 2024





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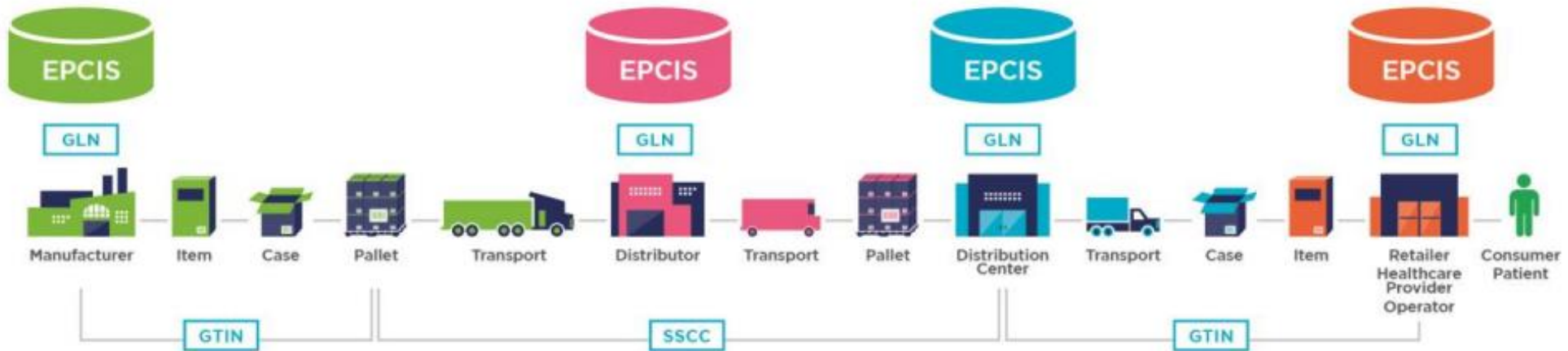
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# Sharing Physical Event Data With EPCIS



## Events are comprised of five dimensions

1 <b>Who</b> owned the product and who owns it now?	<b>Global Location Number (GLN)</b> (urn:epc:id:sgln:030001.111111.0)
2 <b>What</b> products are impacted?	<b>Global Trade Item Number® (GTIN®)</b> (urn:epc:id:sgtin:030001.0012345.11)
3 <b>When</b> did this event occur?	<b>Event Time</b> (2024-12-01T07:45:16Z)
4 <b>Where</b> was the product and where is it now?	<b>Global Location Number (GLN)</b> (urn:epc:id:sgln:039999.999999.0)
5 <b>Why</b> was this observed and at which step?	<b>Business Step</b> urn:epcglobal:cbv:bizstep:receiving



# GS1 Identifiers For Master Data



- Currently, the U.S. FDA issued Labeler code is embedded into the GS1 Company Prefix (GCP).

GS1 Prefix	<b>03</b>
FDA-assigned Labeler Code	<b>61414</b>
GS1 <i>Company Prefix</i>	<b>0361414</b>

- This enables the National Drug Code (NDC) to also be embedded within the GS1 Global Trade Item Number<sup>®</sup> (GTIN<sup>®</sup>).

The GCP is a number that is unique to each member of GS1 US and identifies you as the owner of the brand.

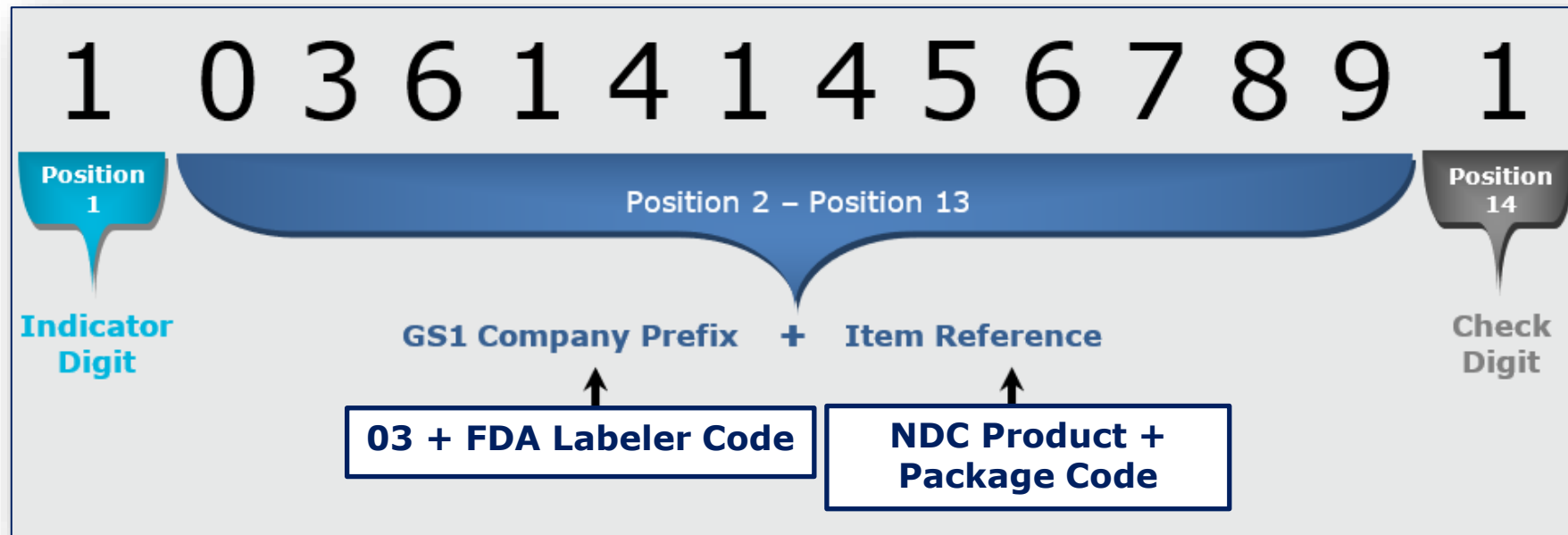
GS1 Company Prefix Length	GTIN Capacity	GLN Capacity	SSCC Capacity
6	1,000,000	1,000,000	100,000,000,000
7	100,000	100,000	10,000,000,000
8	10,000	10,000	1,000,000,000
9	1,000	1,000	100,000,000
10	100	100	10,000,000
11	10	10	1,000,000

# Product Identification: Global Trade Item Number (GTIN)



## The "WHAT"

A GTIN is a GS1 identification key that is used to identify a trade item like your product. It is a globally unique number that is used to identify your specific product throughout the supply chain.



# Difference Between NDC and GTIN

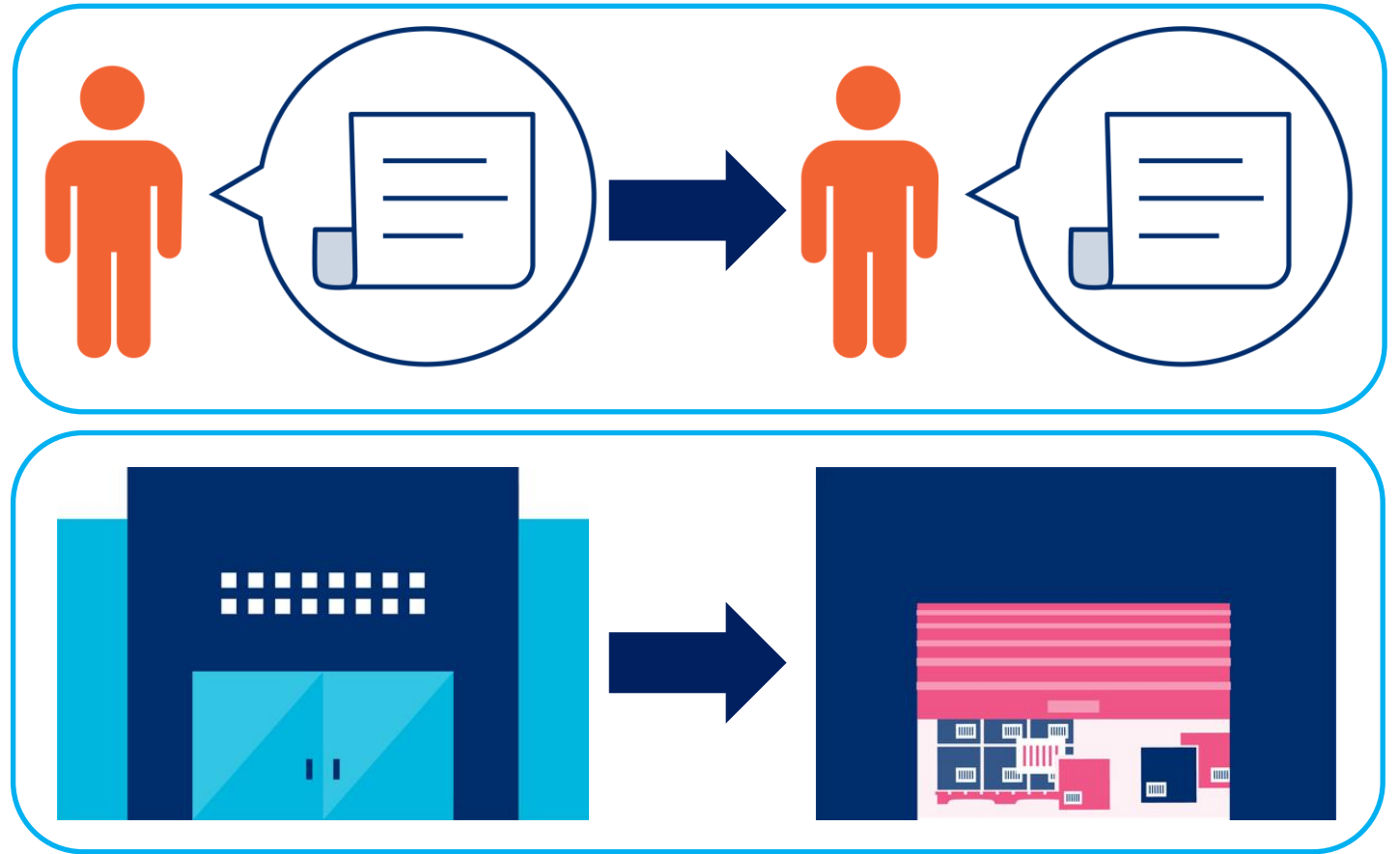


# Location Identification: Global Location Number (GLN)



## The "WHO & WHERE"

A 13-digit number that provides businesses the ability to know who is involved in transactions and where things are located throughout the supply chain. By uniquely identifying parties and locations, GLN helps with tracking products, optimizing processes, and providing greater visibility to transactions taking place around the world.





# Why are GLNs necessary?



**It is used to identify locations, legal entities, and functions in electronic business transactions in:**

- **Electronic Product Code Information Service (EPCIS)** – In FDA’s [DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs, Final Guidance](#), it recommends that trading partners use GS1’s Electronic Product Code Information Services (EPCIS) standard to provide and maintain the electronic data associated with transaction information and transaction statements.
- **Verification Router Service (VRS) solutions** – verification router service refers to using a third-party routing system to send product information back and forth between Trading Partners.





# The ways a GLN is used in EPCIS data for DSCSA:



- Read Point of an EPCIS event - identifies the **physical location where a business process step** took place
- Business location of an EPCIS event - identifies the **physical location where physical objects are**
- Source and destination lists of an EPCIS shipping or receiving event - identify the “**sold by**” and “**sold to**” parties to the transaction and they identify the “**ship from**” and “**ship to**” parties to the transaction
- Business transaction lists of an EPCIS event - uniquely qualify a **business transaction identifier** such as a purchase order number or invoice number
- Master data contained within the EPCIS header of an EPCIS document - **link party and location master data** to the GLNs contained within the EPCIS events
- Standard business document header (SBDH) in the EPCIS header of an EPCIS document - identify the **party sending the message and the receiving party**



# How to Translate a GLN into a SGLN

## ➤ Translate a GLN into a SGLN if it is enumerated from a GCP:

- To translate a GLN that was assigned from a GS1 Company Prefix, you will need to follow this specific data structure: `urn:epc:id:sgln:CompanyPrefix.LocationReference.Extension`
  - An example of GLN assigned from a GCP with a value of 1234567 for the GCP and the GLN value of 1234567890128, the corresponding EPC URN without GLN extension is as follows: `urn:epc:id:sgln:1234567.890128.0`

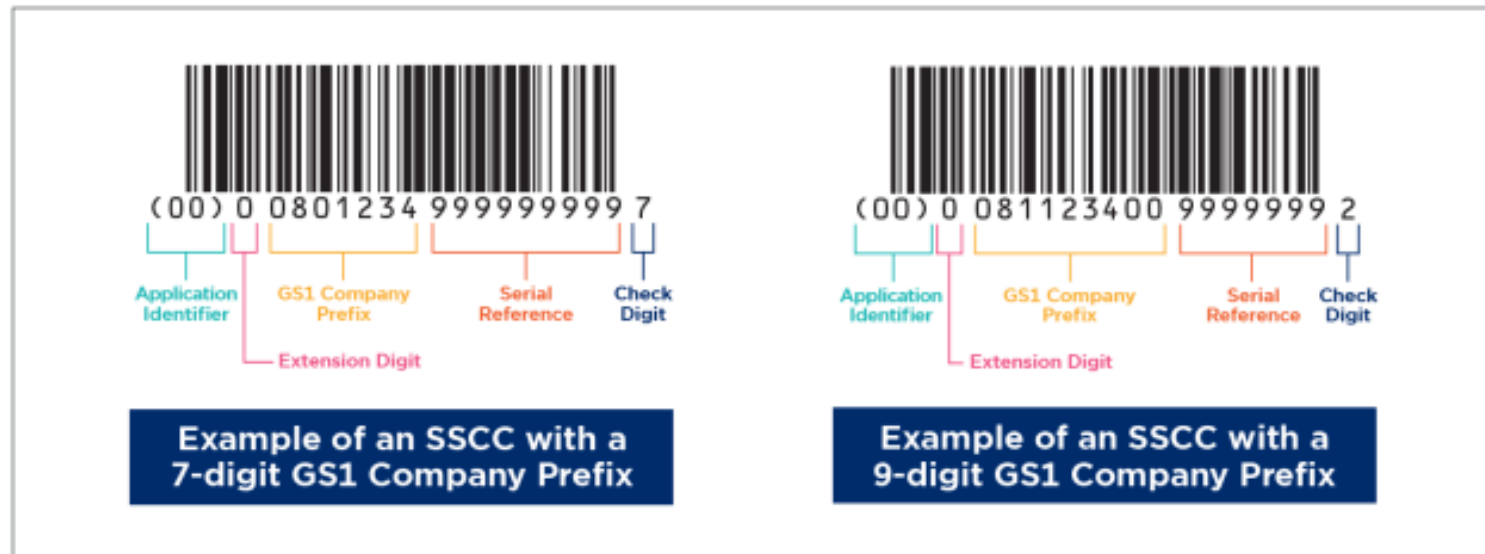
## ➤ Translate a GLN into a SGLN if it is an individually licensed GLN (single GLN) or from the Managed GLN Program (assigned by either your GPO or Wholesale Distributor):

- To translate the GLN, you will need to follow this specific data structure: `urn:epc:id:sgln:CompanyPrefixComponent..Extension`
  - An example of single GLN with no GCP and the GLN value of 1200123456787, the corresponding EPC URN without GLN extension is as follows: `urn:epc:id:sgln:120012345678..0`

# Serial Shipping Container Code (SSCC)



The Serial Shipping Container Code (SSCC) serves as an 18-digit GS1 Identification Key utilized for identifying a logistic unit. Unlike the GTIN, the SSCC functions as a license plate for tracking a shipment of logistics units throughout the supply chain. It represents a valuable tool for enhancing supply chain efficiency and visibility.



**SSCC are not “in scope” for DSCSA but are used by industry and can be an operational requirement.**



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# Contact Information



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# Appendix

# The GS1 DataMatrix



The **GS1 DataMatrix** is required to carry four data elements to meet the requirements of the DSCSA



**GTIN (01) 00361414123410**  
**EXP (17) 2421120**  
**LOT (10) 0192837**  
**SN (21) BLC0485**

- **NDC** (wrapped in the GTIN AI (01))
- **Serial Number** AI (21)
- **Batch/Lot** AI (10)
- **Expiration Date** AI (17)

In the example above, the Ais that are fixed are first followed by the A1s that are variable

# EPCIS Events captured and shared by...



**EPCIS is flexible and extensible**



**Ability to query and verify pharma product requirements**



**EPCIS is global**

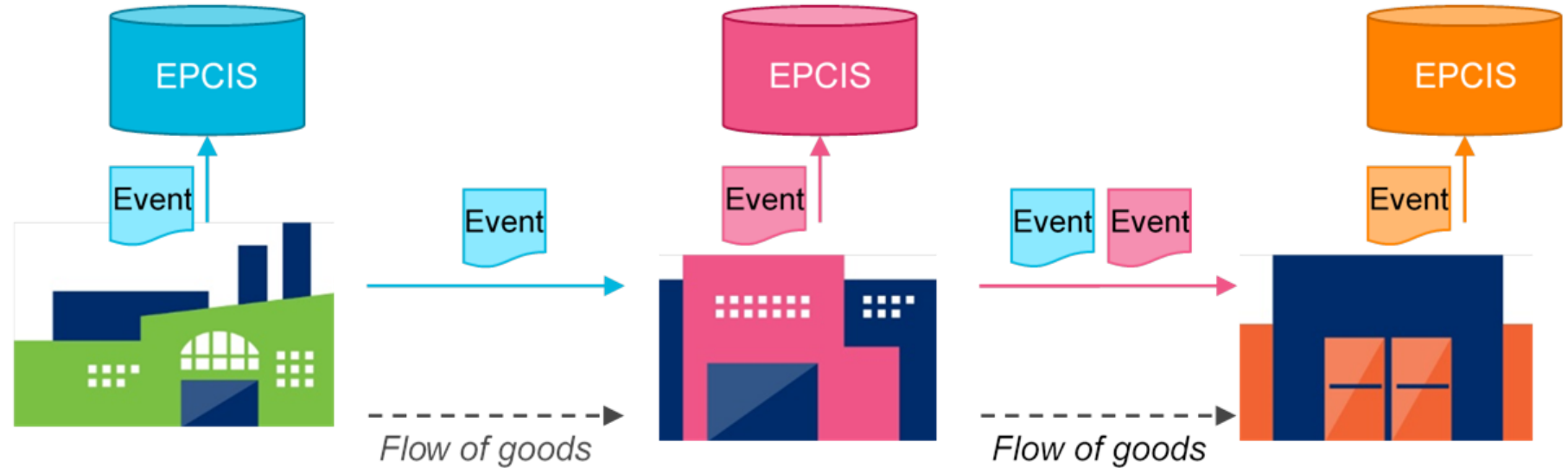


# EPCIS – Sharing of Events

- The Event Identifies the “WHY” and “WHEN”



Decentralized Data Flow Model that enable Trading Partners to share the necessary events downstream



## Standard Leveraged

GS1 Standards and Guideline for EPCIS and CBV

## Operational Use of Standard

Implementation Guideline: GS1 Standards for DSCSA and Traceability

## Scenario Depiction of Oper. Use

Addendum: Guidance and XML Examples for Supply Chain Choreographies in Serialized Item-Level Management

# GS1 US Resources



## Rx Secure Supply Chain Workgroup: 150+ members, 50+ organizations

- Exception Handling Implementation Guideline
- FAQs
- Best Practices for Industry

## DSCSA Webpage

- DSCSA, Guidance by Stakeholder, GLNs, Resources, FAQs

Resource	What It Will Help With
<a href="#">Frequently Asked Questions in Preparing for the U.S. DSCSA</a>	Answering frequently asked questions about identifying, capturing and sharing information to help meet DSCSA requirements.
<a href="#">GS1 US DSCSA Implementation Guidelines</a>	Understanding technical requirements for encoding your product with GS1 Identifiers and how to capture GS1 product identifiers when receiving shipments.
<a href="#">Applying Lightweight Messaging Standard for Verification of Product Identifiers</a>	Configuring PI verification business scenarios and technical requirements for responding to verification requests from your direct and indirect trading partners.
<a href="#">How to Identify your Location for DSCSA Requirements</a>	Identifying your locations with a Global Location Number to share information related to Transaction Information (TI) and Transaction Statements (TS) and verify product information through a third-party routing system.
<a href="#">GS1 US Implementation Guideline for Pharmaceutical Chain of Custody</a>	Capturing GS1 product identifiers when packing and shipping when working with 3rd party agents (CMOs, CPOs, and 3PLs).
<a href="#">GS1 US Pharmaceutical Conformance Test Program</a>	Optimizing the data quality of your EPCIS serialized exchanges with the help of a certified third-party testing service.
<a href="#">GS1 US DataHub</a>	Sharing, searching, and retrieving GLN information with your trading partners.

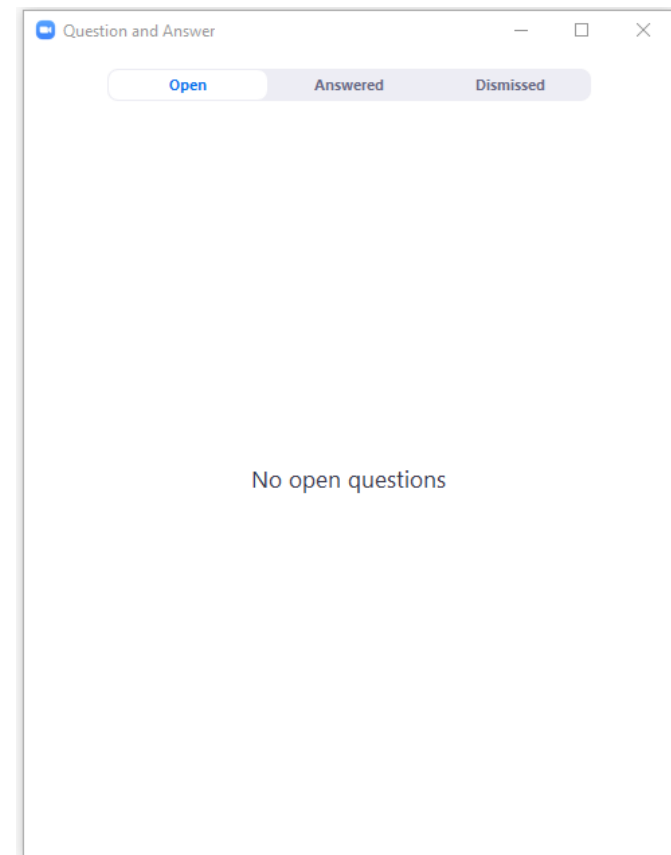
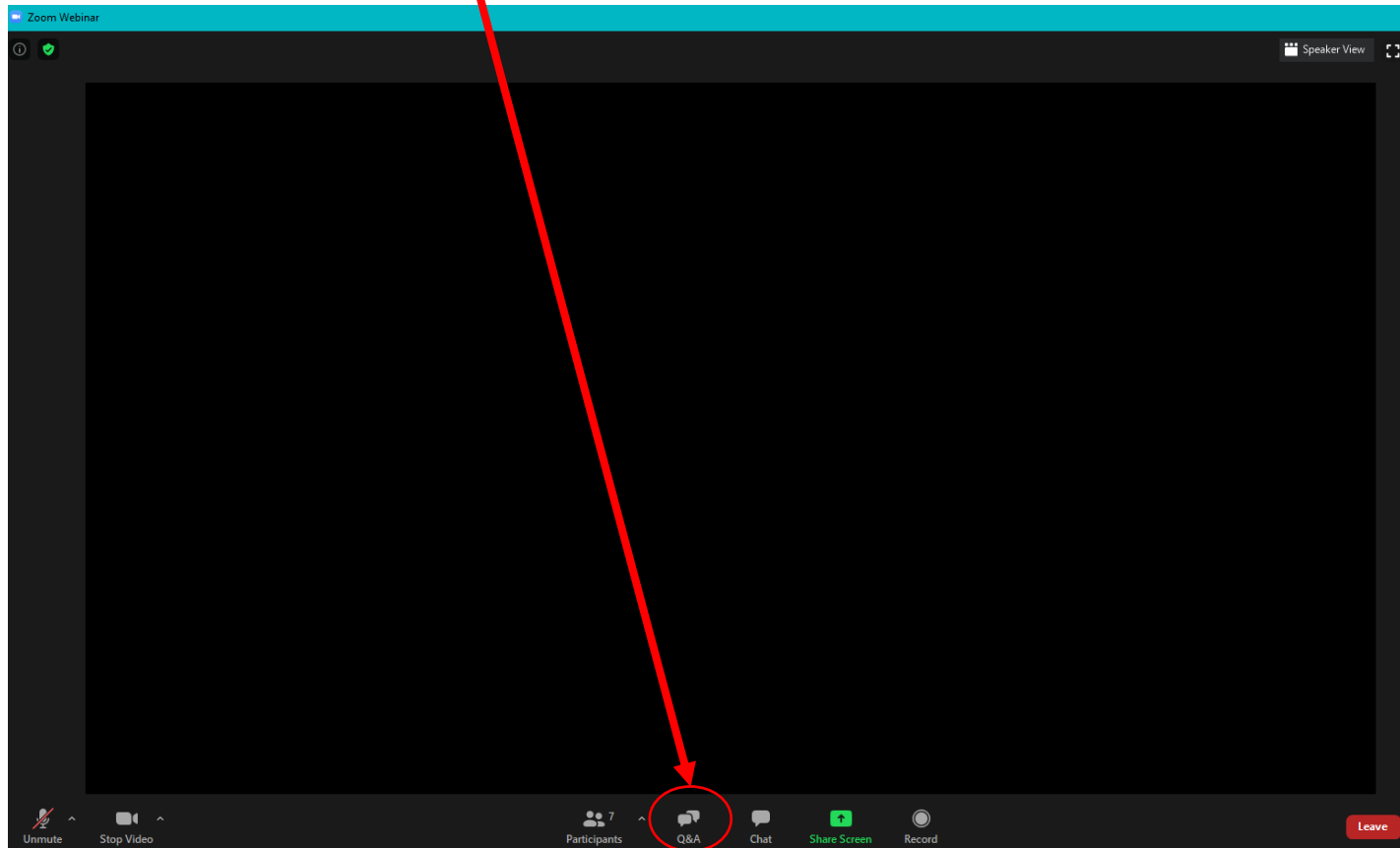
# GS1 Tools



- [GS1 General Specifications](#)
- [GTIN Management Standard](#)
- [GLN Allocation Rules Standard](#)
- [Check digit calculator](#) - Calculate correct check digit for GS1 barcodes.
- [GS1 Database](#) - Verify global identity for products, locations and companies.
- [EPC encoder/decoder](#) - Translate between GS1 identifiers and different Electronic Product Code (EPC) forms.
- [EPCIS Workbench](#) - Create, decode and validate Electronic Product Code Information Services (EPCIS) visibility event data.
- [FREEPCIS](#) - Free EPCIS repository for development and test.

# Questions & Answers

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# Upcoming Events

2024 Traceability Webinar Series | Thursday, July 11, 2024,  
2:00 PM - 3:00 PM ET | VRS: An Overview and Update on VRS  
Improvements

2024 Traceability Webinar Series | Thursday, August 8, 2024,  
2:00 PM - 3:00 PM ET | Ask the Experts – Understanding  
Compliance

2024 Traceability Seminar | August 26—28, 2024 | Marriott  
Marquis, Washington, D.C.

Learn more at [www.hda.org/upcoming-events/](http://www.hda.org/upcoming-events/)

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