



Implementation Reality

“How to fulfill the requirements in California”

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Our experts

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- ***Ron Bone***, Senior Vice President, ***McKesson***
- ***Bob Celeste***, Director Healthcare, ***GS1 US***





A Manufacturer's Perspective

Peggy Staver, Pfizer





Discussion Points

California Mfg Requirements

- Serialization
- e-Pedigree
- Interoperable Electronic System

Challenges

Best Practices

Open Discussion





Challenges

Serialization

- Internal and External (CMO) Network
- Colliding Global Requirements
- Limited Resources
- Aggregation and the Use of Inference

e-Pedigree

- Basic Architecture Decisions
- DPMS vs. EPCIS
- “Big Data” Issue
- Certification?
- Digital Signatures?





Challenges

Interoperable Electronic System

- Doesn't Exist Today
- Remaining Time to Implement
- Limited Pharmacy Engagement
- Varying legacy systems
- Different Solution Providers
- Limited Resources
- Scalability of Piloted Solutions?





Best Practices

Understand Requirements

- Engage with CA BoP
- Contribute to Regulation Development

Secure Senior Management Support

Obtain Funding and Necessary Personnel

Establish Cross Functional Team

- Develop Your Strategy
- Communicate requirements to internal sites and external partners (CMO's)
- Build flexible solutions to meet global requirements
- Adopt standards-based, non-proprietary solutions

Test, Test and Test Again (End-to-End)!!!



A Wholesaler's Perspective

Ron Bone, McKesson





Challenges

- We are 14 months from the first phase of implementation without clear guidance on the interoperable data exchange system.
- There are two incompatible electronic systems (DPMS and EPCIS) being implemented by manufacturers.
- Only a few manufacturers have been in a position to pilot with us.
- We don't have engagement from the provider community in pilots.





Challenges (Continued)

- At what point(s) in the warehouse process will unit level scanning be required.
- What will be an acceptable use of inference?
- What is the certification requirement?
- How will our downstream partners gather the pedigree information to be able to process a return – variability in capability?
- Will our downstream partners be allowed to use inference on the totes we ship?



Best Practices

- Shift your thinking about products by SKU/Lot to thinking about products as a unique individual unit.
- Select experienced traceability service provider (best if they can handle DPMS and EPCIS).
- Begin pilots as soon as possible:
 - Readability of 2D Barcode
 - Exchange data between trading partners – Our experience is that this is critical
- Find out what works and what does not work before investing Capital.



Best Practices (Continued)

- Develop open dialog with experienced trading partners.
- Develop SOP's:
 - How will serialized products be handled?
 - When will cases be opened in the warehouse?
 - Steps to be taken when a serial number is not in the database received.
 - Exception processing.
 - How will inference testing be conducted?
- Provide downstream partners clear expectations on submitting returns.





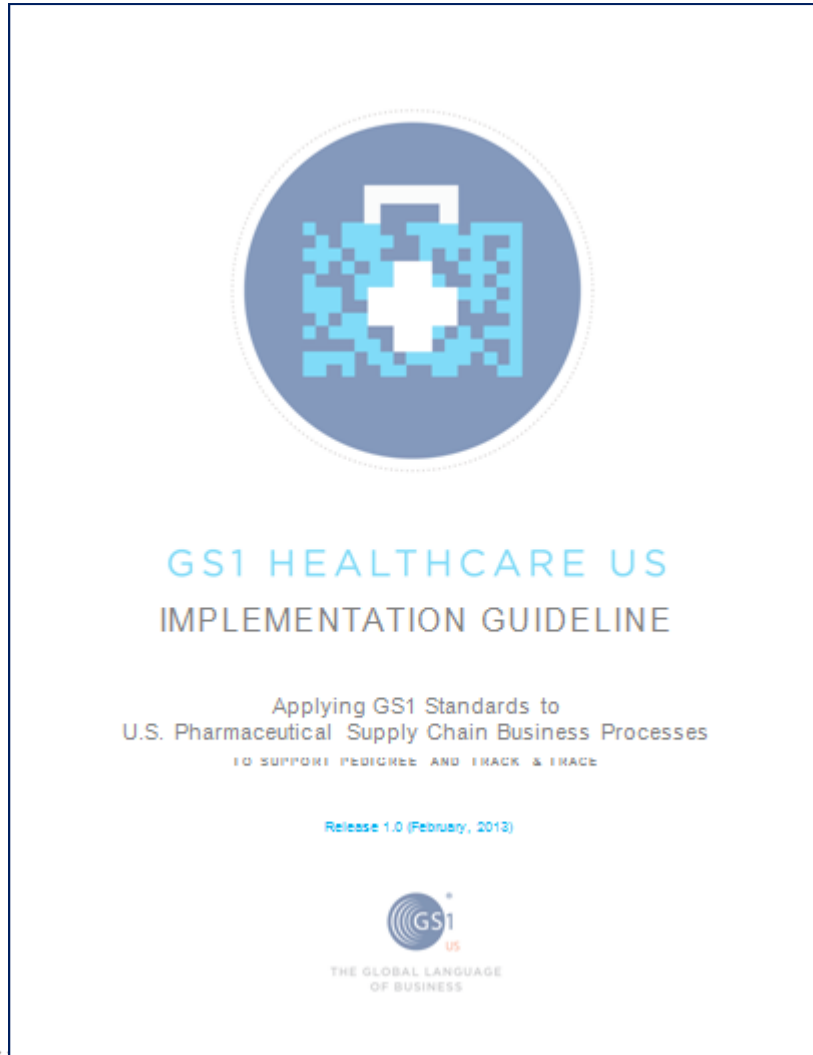
A SDO's Perspective

Bob Celeste, GS1 US



SECURE SUPPLY CHAIN TASK FORCE

RX IMPLEMENTATION GUIDELINE



www.gs1us.org/RxGuideline

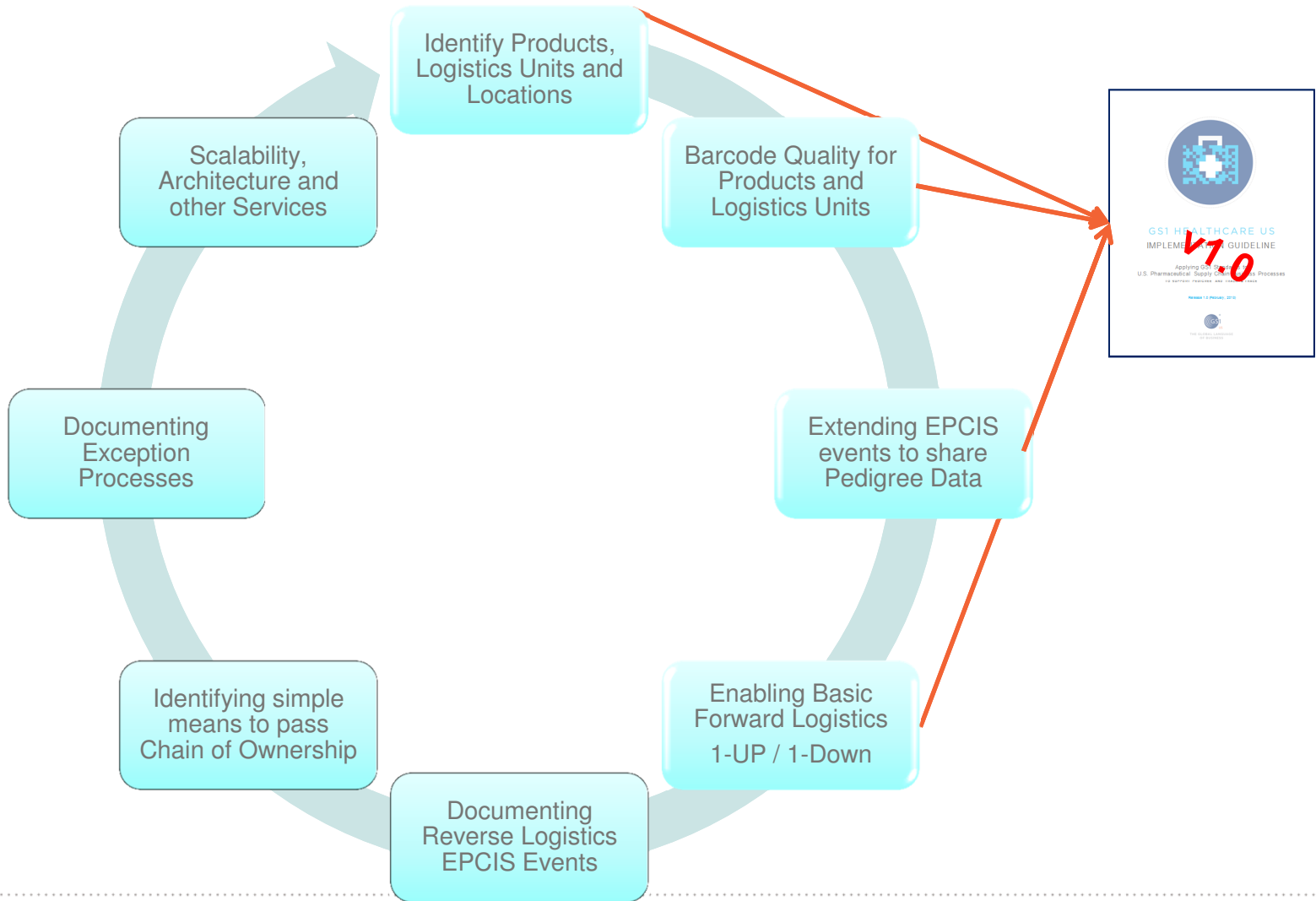
Contents of v1.0:

- Identifying Trade Units (Products, Cases, and Kits):
- Identifying Logistics Units (Cases, Pallets, and Totes)
- Identifying Parties & Locations
- Encoding GS1 Data Carriers
- Translating Captured Data
- Master Data Management (product and location)
- Applying GS1 Standards for Event Data
- Supply Chain Events to be Captured for Pedigree

Continuing work on v2.0

- **Exceptions Processing**
- Pilot findings / best practices
- Forward Logistics Examples
- Reverse Logistics Examples
- Potential Architectural Models

SECURE SUPPLY CHAIN TASK FORCE RX IMPLEMENTATION GUIDELINE



SECURE SUPPLY CHAIN TASK FORCE RX IMPLEMENTATION GUIDELINE

Identify Products,
Logistics Units
and Locations

Scalability
Architecture

Barcode Quality for
Data and



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4. Background Concepts

4.1. Relationship between NDC – GTIN – SGTIN

The FDA National Drug Code (NDC) is a U.S. regulatory identifier used to identify pharmaceutical products for regulatory purposes. The GTIN is a supply chain identifier used to identify *products* for supply chain purposes. The SGTIN is a supply chain identifier used to identify *individual instances of a product* for supply chain purposes. There is a cohesive, hierarchical relationship between these identifiers. As illustrated in Figure 1, NDCs can be embedded into GTINs so that identification of pharmaceutical products for supply chain purposes is consistent with identification of pharmaceutical products for regulatory purposes. GTINs can then be supplemented with serial numbers to identify individual instances of the pharmaceutical product.



Figure 1: Relationship of the NDC, GTIN and SGTIN

4.2. NDC Labeler Code & GS1 Company Prefix


The NDC is a 10-digit identifier comprising two segments: a *Labeler Code* assigned by the FDA and a *Product/Package Code* assigned by the manufacturer. The *Labeler Code* is a variable length identifier assigned by the FDA (and encoded into NDCs) to identify a company that manufactures a drug (including







SECURE SUPPLY CHAIN TASK FORCE RX IMPLEMENTATION GUIDELINE



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 **Human Understandable Text Below A Barcode:** Many pharmaceutical companies are including text below the barcode that is more readily understandable by healthcare clinicians and supply chain personnel. Here are some examples:

		
GTIN 00314141999995 SN 10000000234 LOT 987654321GFEDCBA EXP 01/2015	GTIN 00314141999995 SN 10000000234 EXP JAN 2015 LOT 987654321GFEDCBA	GTIN 00314141999995 SN 10000000234 EXP 25 JAN 2015 LOT 987654321GFEDCBA

8.1.1. Trade Items: Products, Cases & Kits

As a way of gaining uniformity throughout the supply chain, this guideline includes two best practice barcode options for products, cases and kits: GS1 DataMatrix and GS1-128. There are two required data elements to be encoded: GTIN and Serial Number.

ing EPCIS
to share
ee Data

SECURE SUPPLY CHAIN TASK FORCE RX IMPLEMENTATION GUIDELINE

Identify Products,
Logistics Units and

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❖ Extensions used in Commissioning Events:

In addition to the EPCIS standard fields shown above, the following extensions are also included in a Commissioning event. (See Section 15 for general notes about extensions.)

Element	Usage	Type	Value
<u>eventID</u>	Optional	String	<p>A universally unique identifier (UUID) as defined by IETF RFC 4122 that uniquely identifies this event, using the URN syntax also defined in RFC 4122.</p> <p>Currently this event ID is added here for the purposes of pilots to test the use and value of an ID for identifying and referencing EPCIS events (void, replace, etc).</p> <p><i>It is possible that this attribute will be adopted into the EPCIS standard and promoted to the standard set of attributes. At that time, this attribute will be removed from the extension as part of a future version of this guideline.</i></p>
<u>additionalTradeItemIdentification</u>	Conditional	<u>AdditionalTradeIdentificationType</u> (see below)	The product code associated with all of the EPCs in the <u>epcList</u> of the <u>ObjectEvent</u>
<u>tradeItemMasterData</u>	Conditional	Complex Type <u>tradeItemMasterData</u> (see below)	Used for trading partners who do not employ a master data management strategy
<u>lotNumber</u>	Conditional (see notes below)	String	The lot or batch number for all of the EPCs in the <u>epcList</u> of the <u>ObjectEvent</u>
<u>itemExpirationDate</u>	Conditional (see notes below)	Date	The expiration date for all of the EPCs in the <u>epcList</u> of the <u>ObjectEvent</u> , formatted as an <u>xsd:date</u> .*

Improve Quality for
Products and
Logistics Units

Extending EPCIS
Events to share
Pedigree Data

Basic
Logistics
-Down



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19.1.1. Ship a full case through the supply chain

The following examples depict a Manufacturer shipping a pallet of cases to a Wholesaler who then breaks the pallet down to its cases and ships a full case to the Dispenser warehouse.

In the Figure 19 scenario, each trading partner captures the correct EPCIS events; however, they only share the *Shipping* event with each other. (If necessary, each trading partner could collect the remaining events from their trading partners to assemble the full history of events for a particular trade item.)

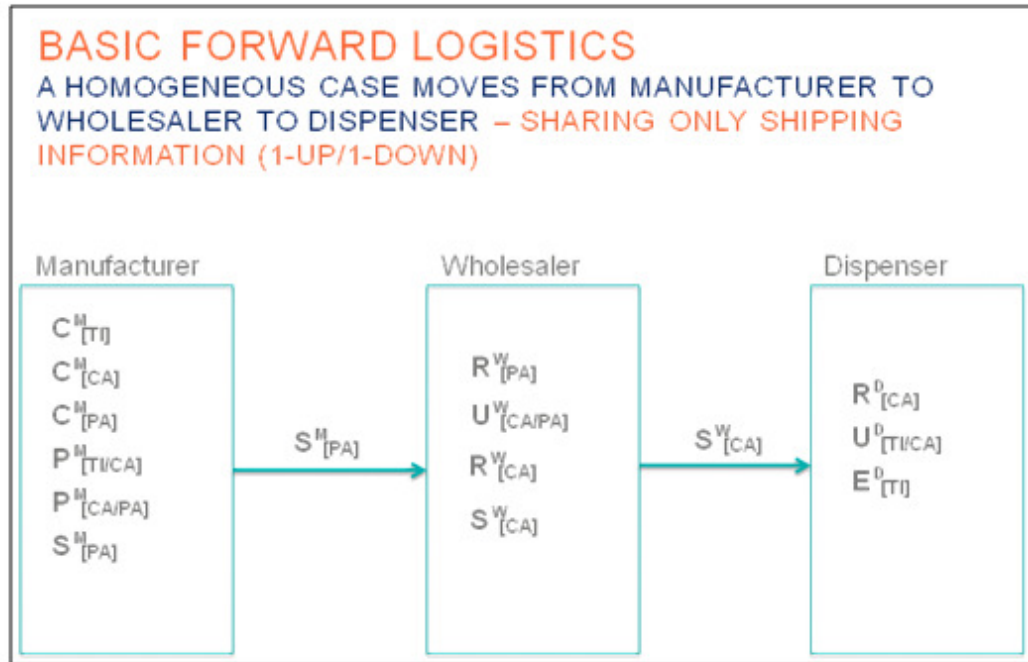


Figure 19: Ship full case through supply chain – sharing Shipping events only

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Release 1.0 (February, 2013)

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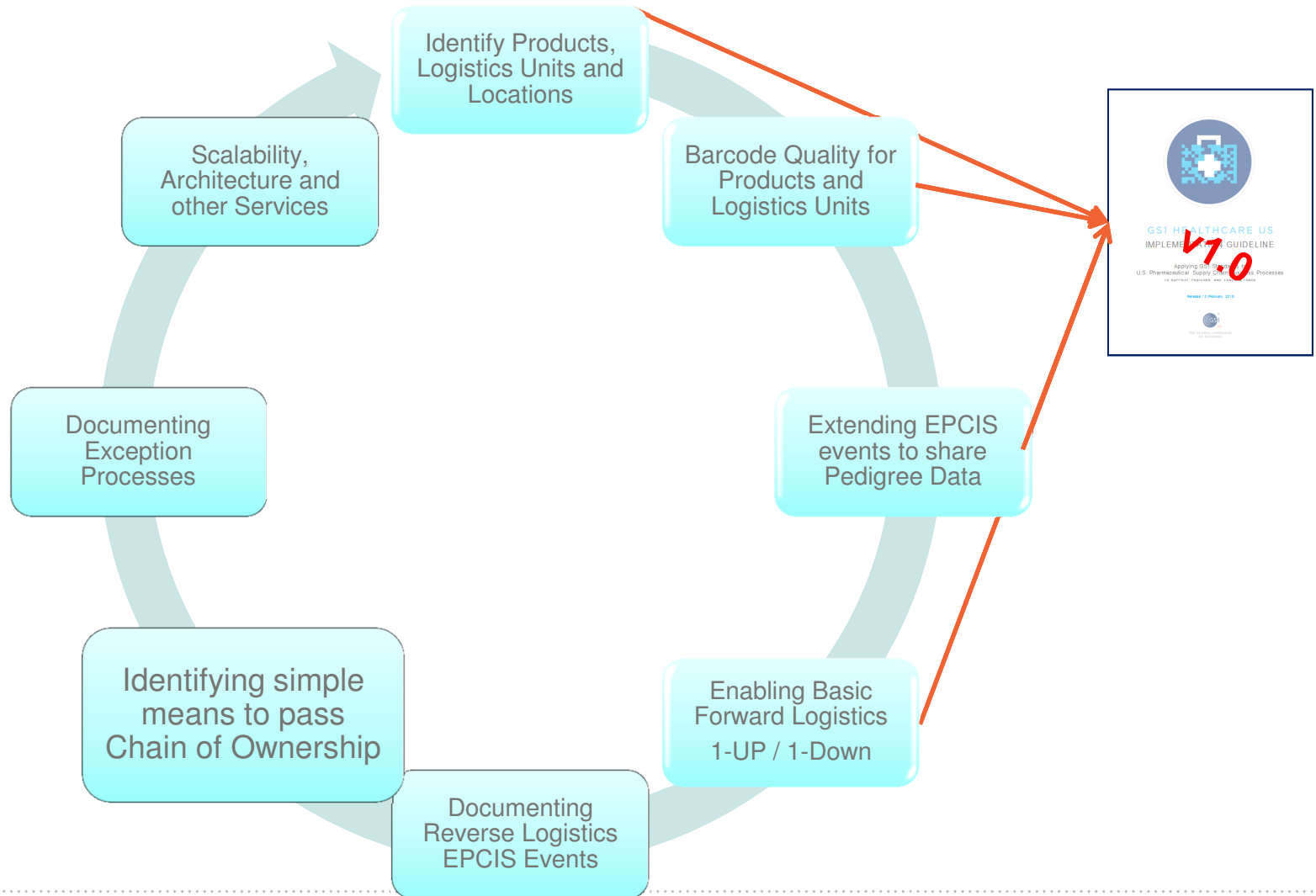


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Enabling Basic Forward Logistics 1-up / 1-Down

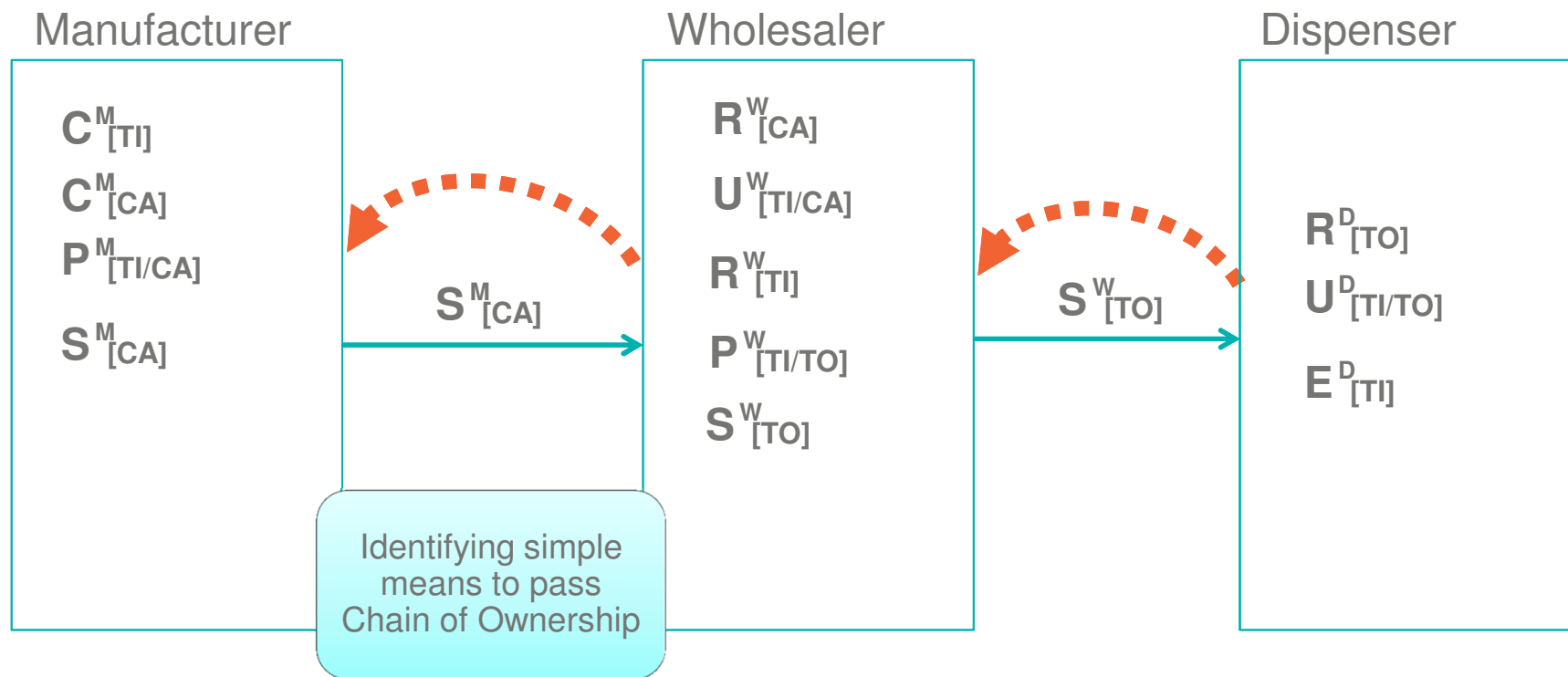
Documenting Reverse Logistics EPCIS Events

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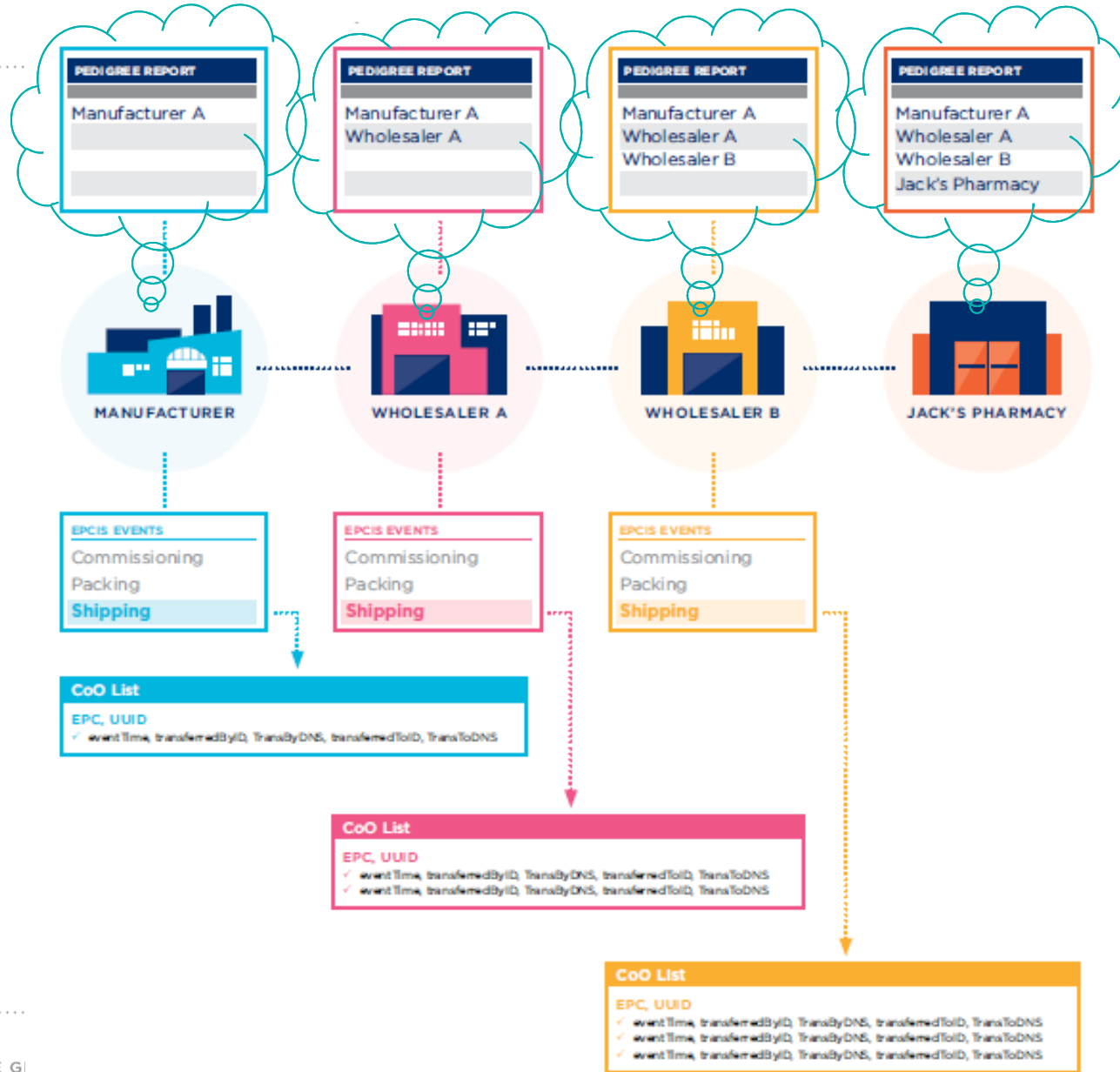


RX SECURE SUPPLY CHAIN

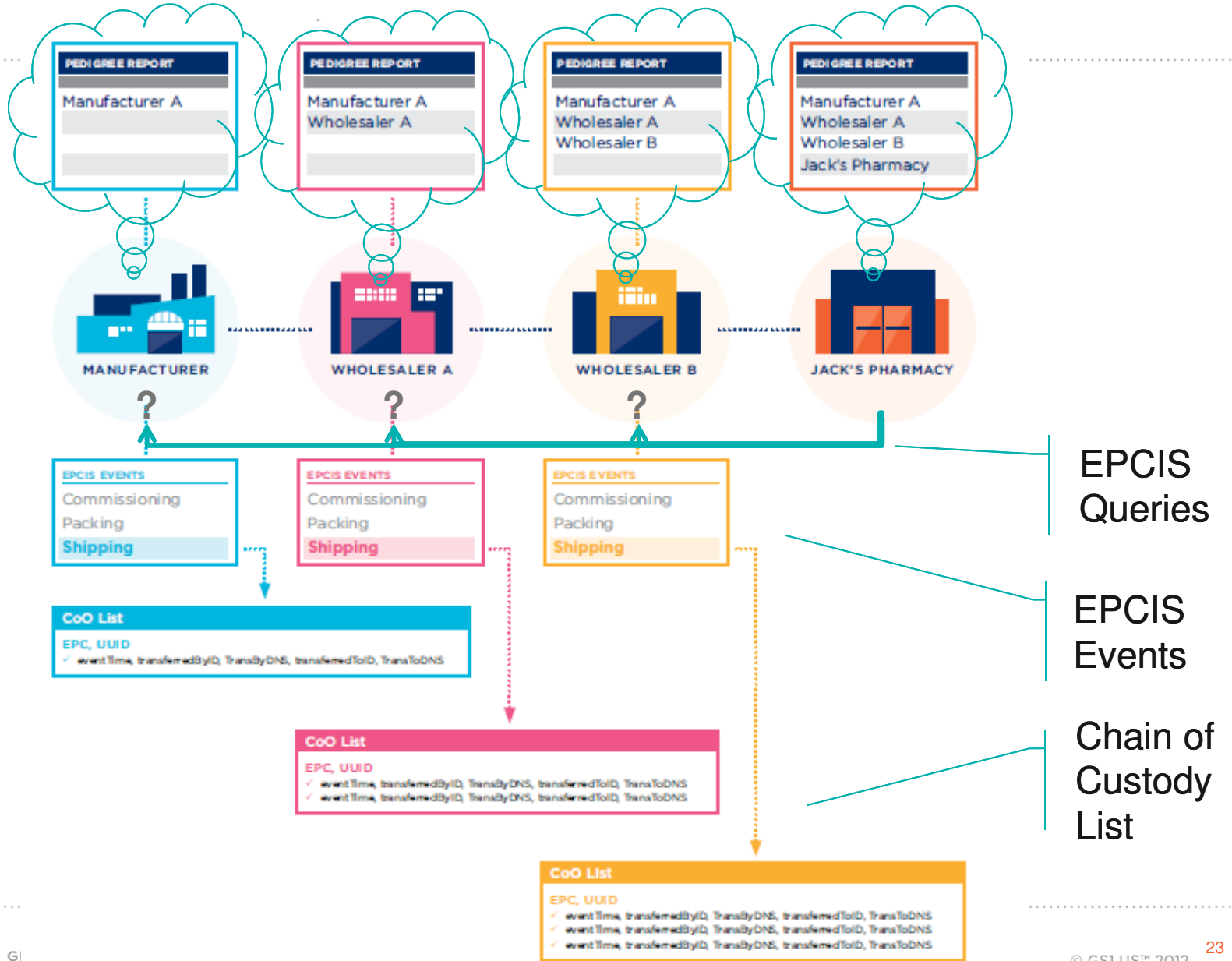
WHAT IS THE SIMPLEST WAY TO SHOW THE CHAIN OF OWNERSHIP OR CHAIN OF CUSTODY?



EPCIS BASED PEDIGREE CONCEPT



EPCIS BASED PEDIGREE CONCEPT





Open Discussion





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