

Verification of Saleable Returns under the DSCSA

Scott Mooney, Vice President Distribution Operations

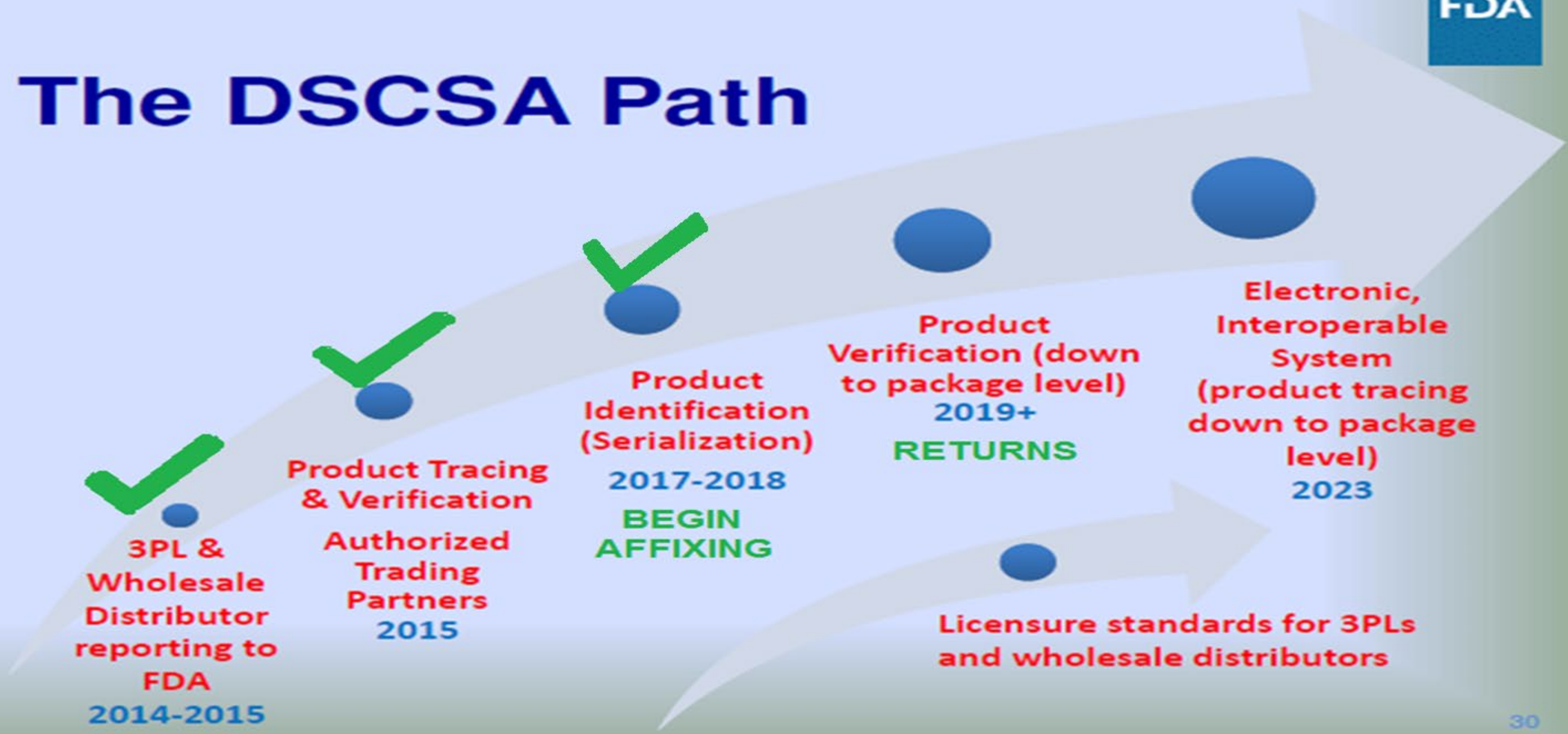
McKesson Corporation

35th Global GS1 Healthcare Conference

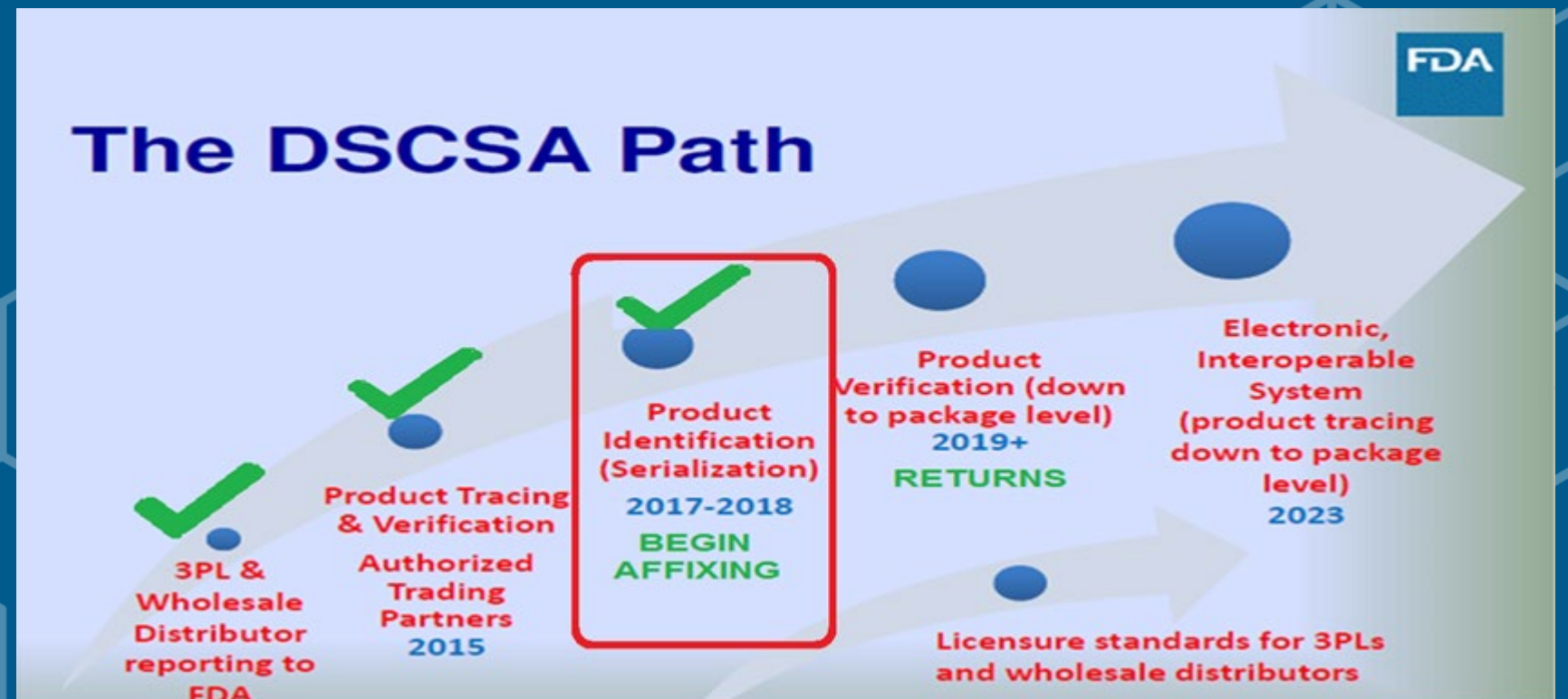
Thursday, March 28, 2019



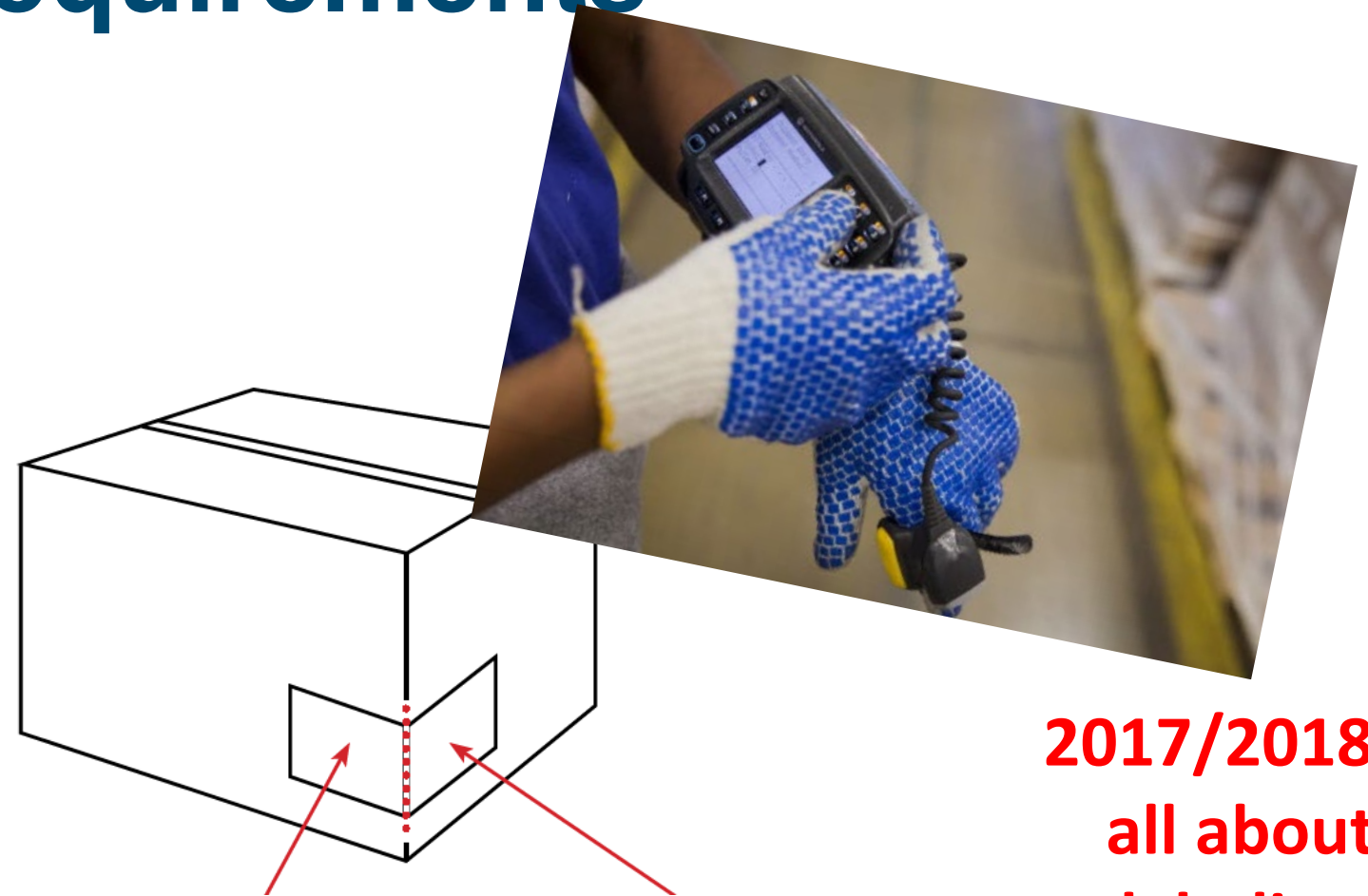
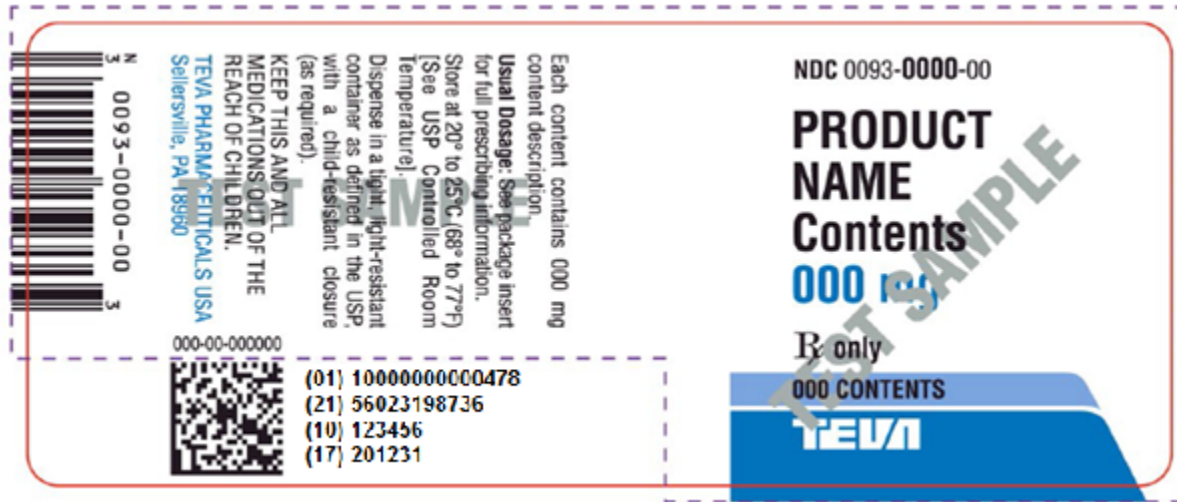
The DSCSA Path



2017/2018 Requirements Underway: Product Marking



DSCSA 2018 Labeling Requirements



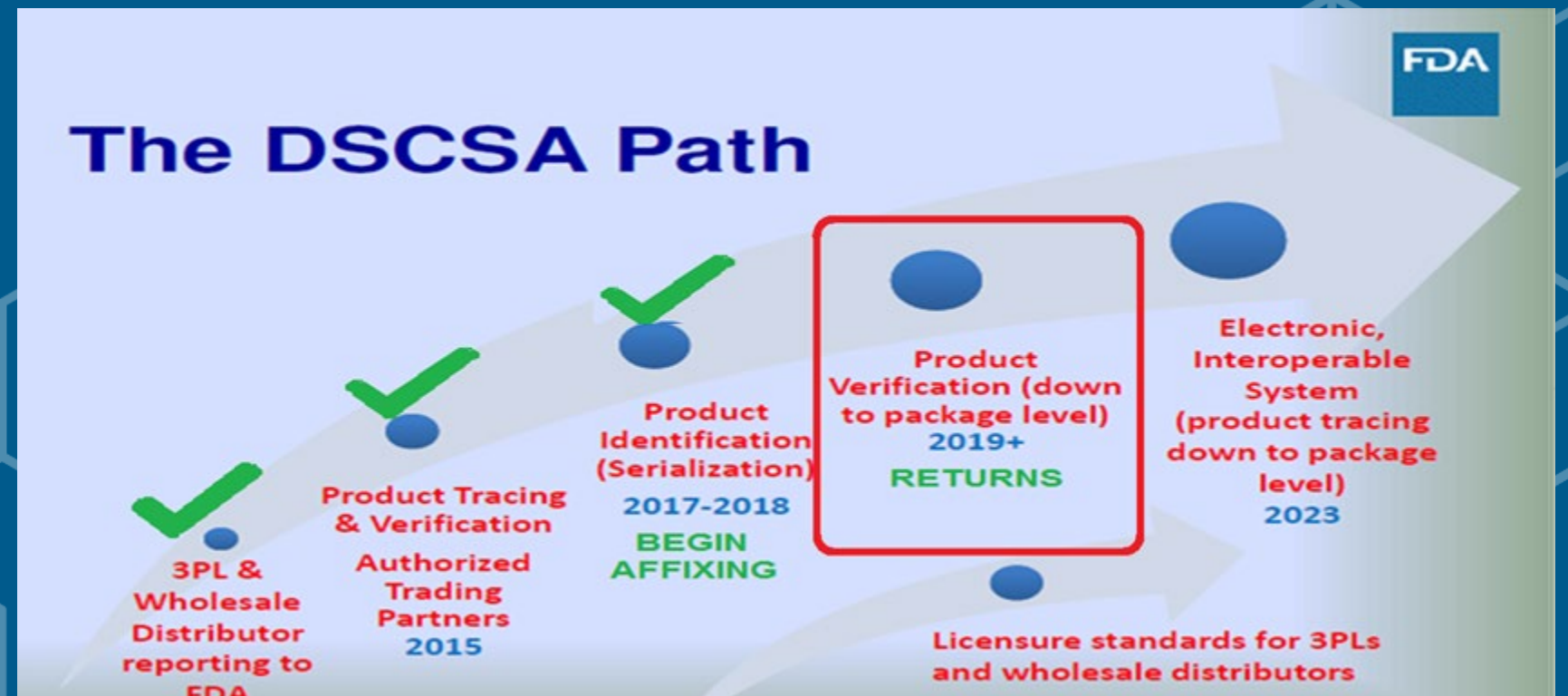
2017/2018 is all about labeling product and NOT passing serialized data

Product Labeling Guidances Issued



- Product marked with a 2D bar code containing:
 - GTIN/NDC, Serial, Lot, Expiry
- Manufacturers received Enforcement Discretion allowing them to delay until Nov 2018 to begin affixing new 2D bar codes
- Manufacturers and repackagers received Grandfathering Guidance allowing them to continue to sell unserialized product packaged before Nov 2018

2019 Requirements under Development: Returns Verification



NEW Returns Requirements

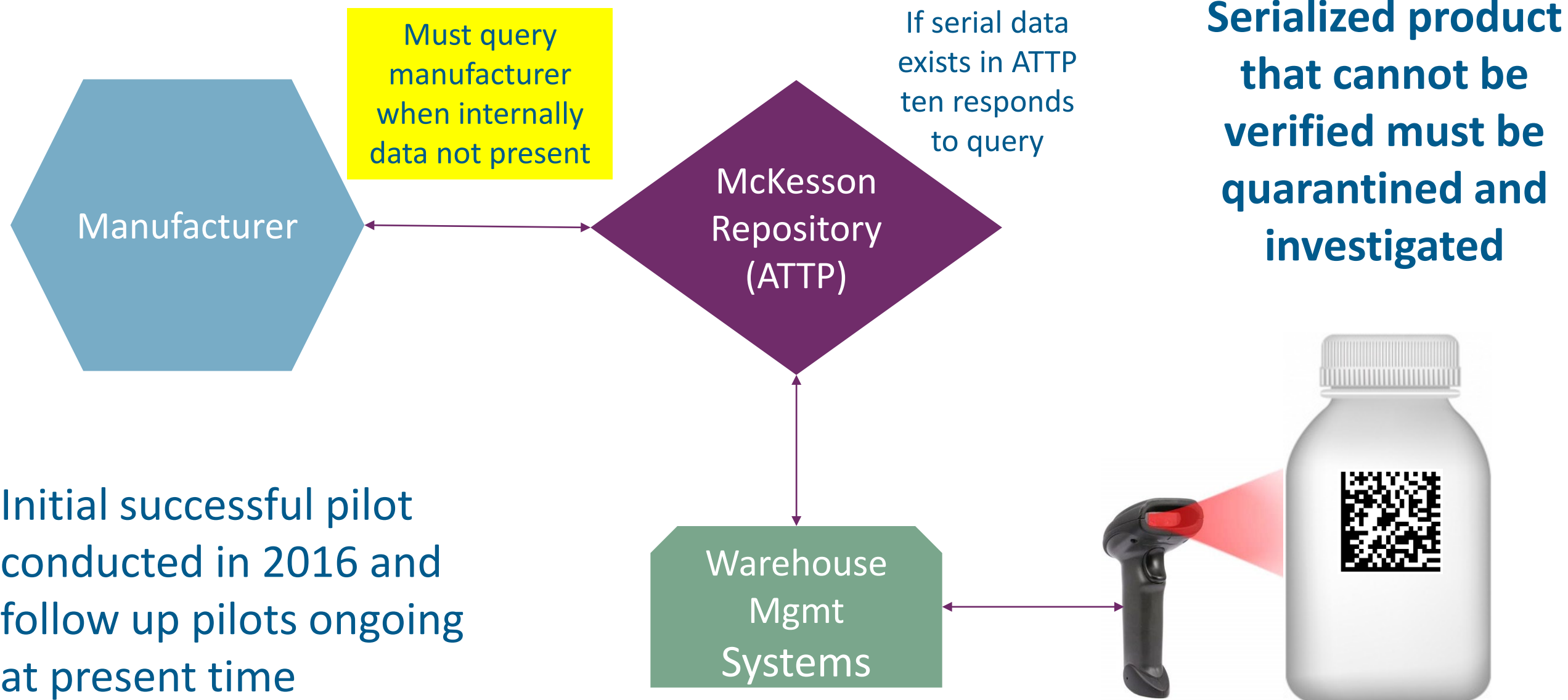
- 1) Distributors must associate the original Transaction Information, Transaction History and Transactional Statement with a saleable return.
- 2) Verify that the product identifier affixed to the product corresponds with the data the manufacturer assigned.
 - Manufacturers can send serialized data for their shipments to their trading partners to be used for verification of future saleable returns
 - OR---**
 - Manufacturers can make serial data available for query using a Verification Router Service requesting data for the distributors

Annual saleable returns in US estimated at 60 million pieces across the industry

McKesson saleable returns approximately 19 Million per year

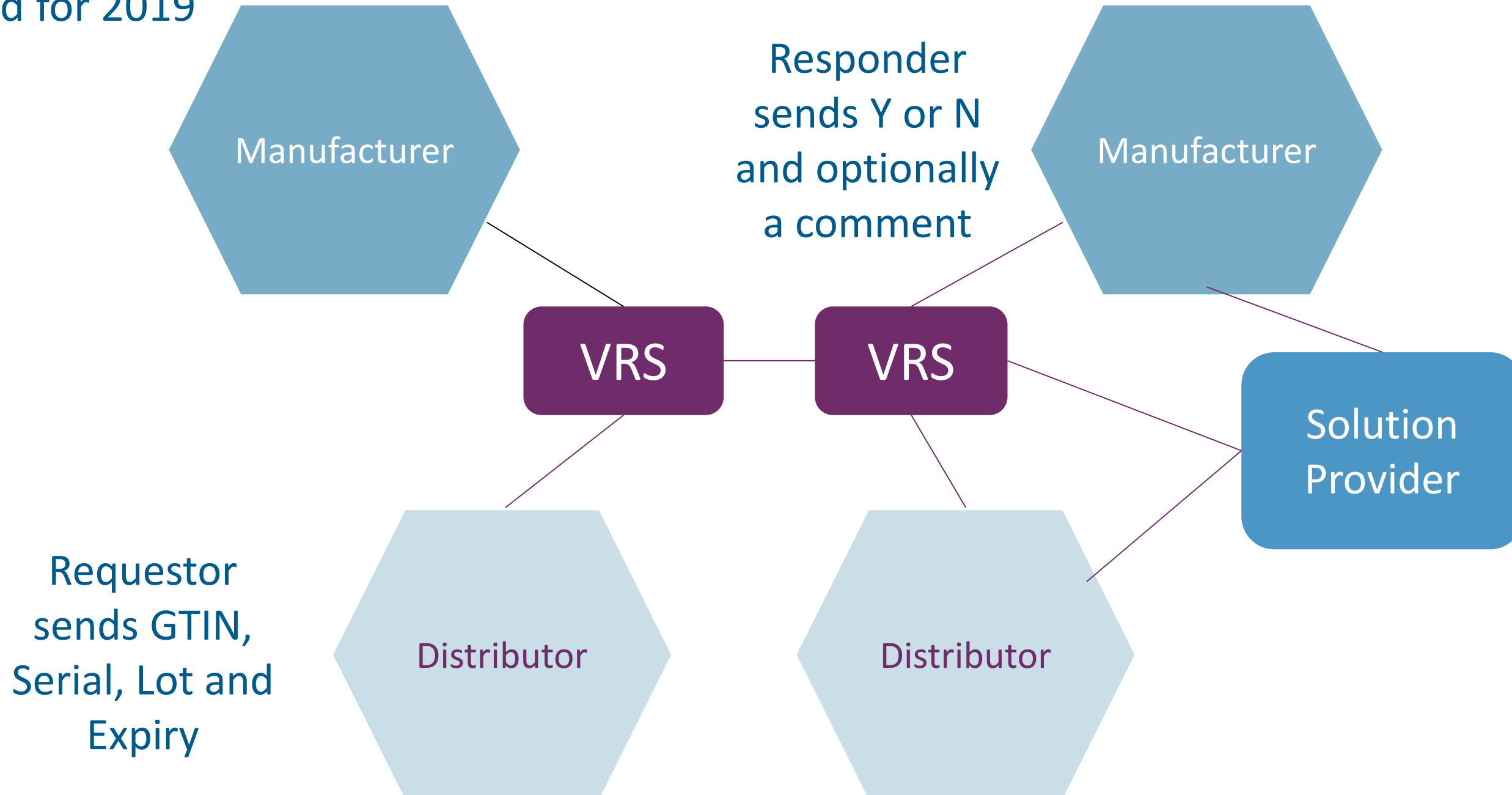


Returns Verification



DSCSA Verification Router Service

Needed for 2019



DSCSA Verification Router Service

Needed for 2019



Journey to Verification Messaging Standard

Collaboration between GS1 Global, GS1 US & HDA VRS Taskforce



GS1 Verification Messaging Standard

Designed for global cross sector use

- Driven by urgent (Nov 2019) DSCSA deadlines, but developed as a **generic lightweight framework** that will support use and extension by other sectors (e.g. food, technical industries) in distinct regulatory jurisdictions
- Specifies a standardised, *simple* (“lightweight”) messaging framework that foresees:
 - verification request and response
 - provision of actionable information that enables the requestor to determine whether to accept, reject, or quarantine the product

GS1 Verification Messaging Standard

Positioning within GS1 Architecture

- Verification Message as new addition to the 'Share' layer
- First ever GS1 "Share" standard to...
 - leverage the new GS1 Digital Link standard (verification request syntax)
 - include JSON as a message response syntax (verification response syntax)

GS1 Verification Messaging Standard

What is GS1 Digital Link?

GS1 Digital Link provides a Web-friendly way to express any GS1 identifier (including compound keys) and associated data attributes as a Web URI that works on the Web and enables retrieval of associated information through a straightforward Web request (HTTP GET)

(01)00361414567894(10)400806(21)1908642E(17)170728



translation

<https://id.gs1.org/01/00361414567894/10/400806/21/1908642E?17=170728>

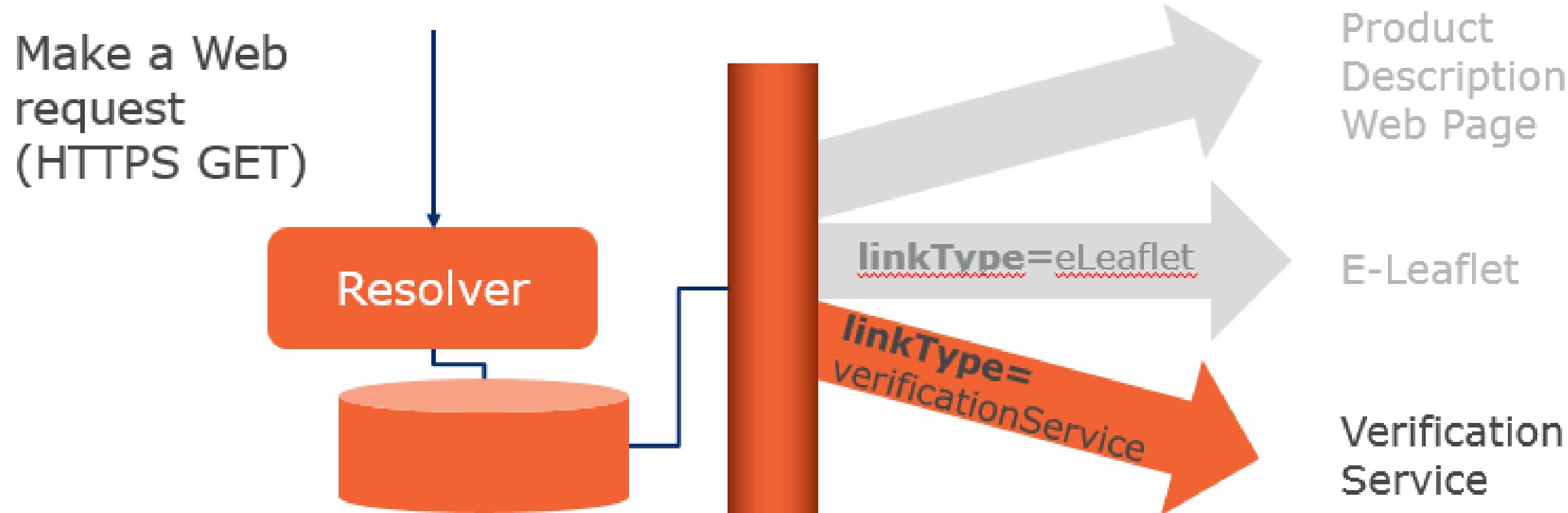
<https://id.gs1.org/gtin/00361414567894/lot/400806/ser/1908642E?exp=170728>

<https://example.com/gtin/00361414567894/lot/400806/ser/1908642E?exp=170728>

GS1 Verification Messaging Standard

Redirection of GS1 Digital Links

<https://id.gs1.org/gtin/00361414567894/lot/400806/ser/1908642E?exp=170728>



GS1 Verification Messaging Standard

Verification Requests

- In the DSCSA context, a product instance can be uniquely identified by the following four data elements:
 - GTIN - AI (01)
 - Serial Number - AI (21)
 - Batch/Lot Number – AI (10)
 - Expiry – AI (17)

...encoded in a GS1 DataMatrix as (01){gtin}(17){exp}(10){lot}(21){ser} ,

where {gtin}, {exp}, {lot}, {ser} are placeholders for actual values,

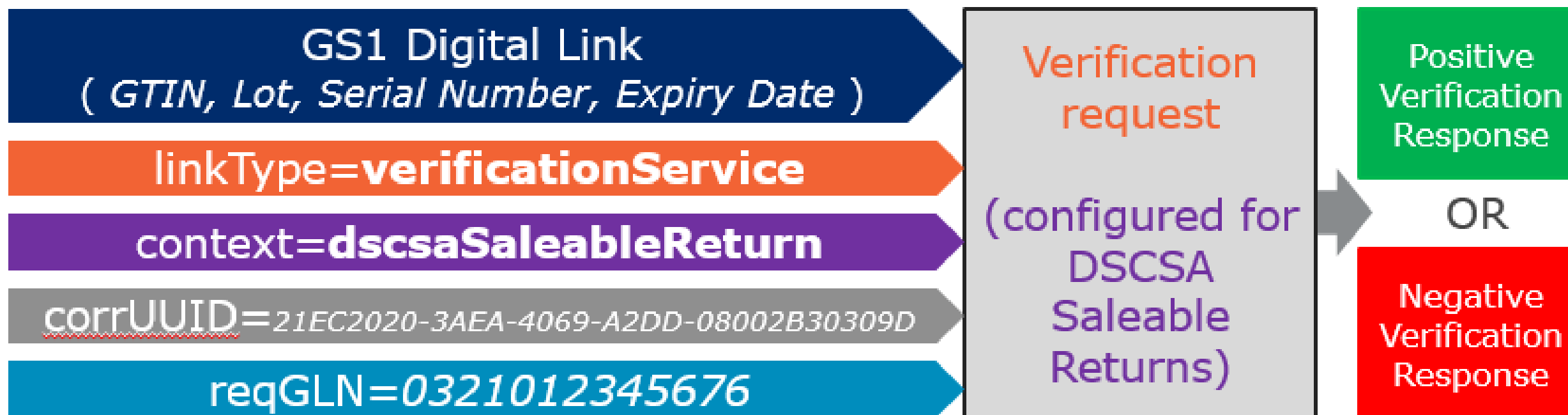
e.g.: (01) 00361414567894 (17) 170728 (10) 1908642E (21) 400806



GS1 Verification Messaging - Requests

use of linkType to request specific type of information service

https://id.gs1.org/**gtin**/00361414567894/**lot**/1908642E/**ser**/400806?**exp**=170728
&linkType=verificationService
&context=dscsaSaleableReturn
&corrUUID=21EC2020-3AEA-4069-A2DD-08002B30309D
&reqGLN=0321012345676



GS1 Verification Messaging Next Steps

Q1/2019

GS1 US Rx workgroup development of Implementation Guideline for Verification Messaging Standard as part of the forthcoming revision (R1.3) of the GS1 US DSCSA guideline / application standard

Q2/2019

Target transition from HDA VRS Request / Response specification to GS1 Verification Messaging Standard



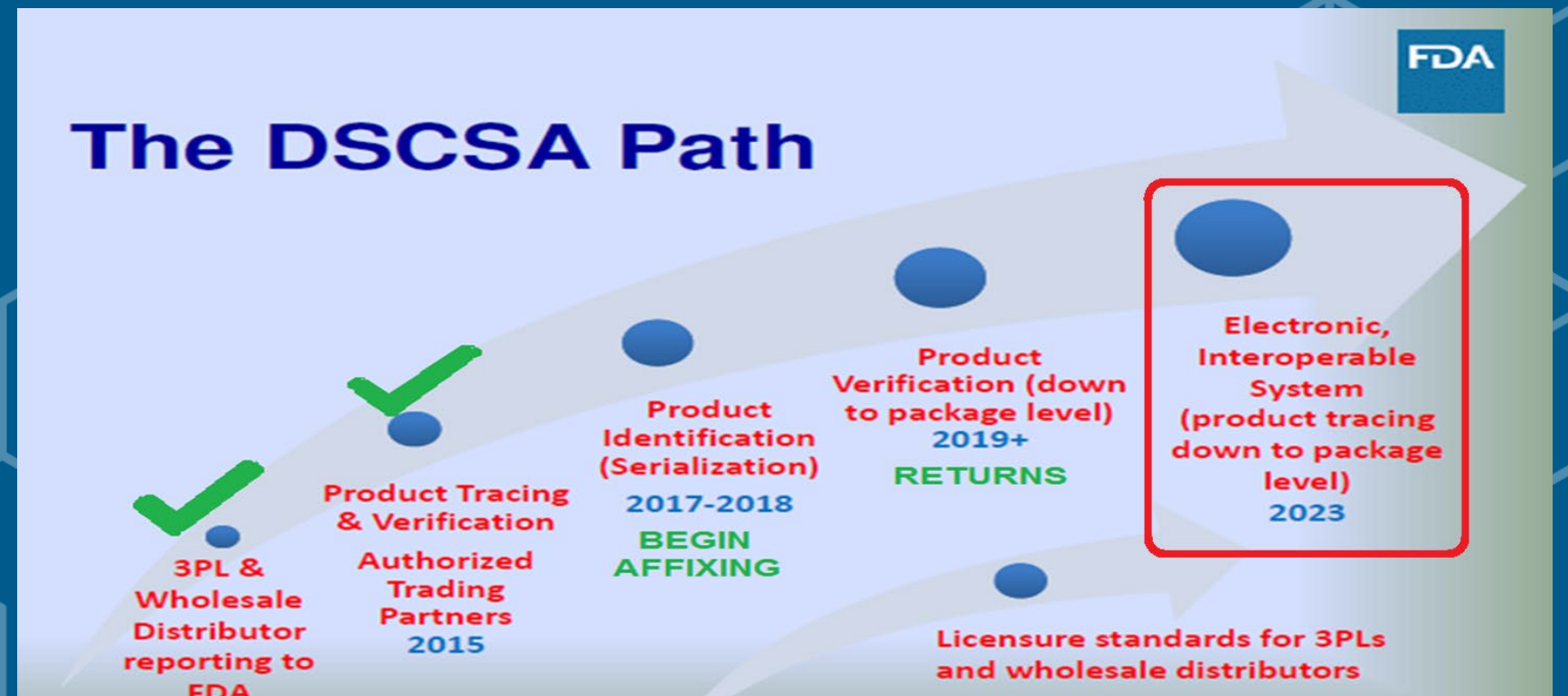
HDA and Industry Next Steps

- Solution Providers adopt new messaging standard in to their systems
- HDA exit planning for Verification Router Service
- Long term governance yet to be determined

Thank you!

- Many companies and team members participated in this effort
- Especially though...
 - Craig Alan Repec and Mark Harrison of GS1, Peter Sturtevant of GS1 US,
 - Jeff Denton of Amerisource Bergen, Elizabeth Waldorf of TraceLink and Allison Sheldon of Pfizer

2023 Requirements: Exchanging Serialized DSCSA Data



Serialized DSCSA Data Exchange

- Historical information sunsets in DSCSA transaction data
- Serial number, Lot Number and Expiry become mandatory in DSCSA transaction data
 - Applies to inbound receiving and outbound sales
 - Significant increases in bar code data capture needs

Questions?