

# Implementing End-to-End Verification Processes with Verification Router Services (VRS)

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# Verification Under DSCSA - Regulatory and Business

## DSCSA Verification Requirements

- Receive and respond to verification requests
- Verification requests may be for:
  - Saleable Returns
  - Suspect or Illegitimate Product Updates
- Verification systems must support industry standards
- Verifications check 4 data elements on the 2D barcode
  - GTIN
  - Serial Number
  - Lot Number
  - Expiration Date

Manufacturers must have systems in place that will allow them to respond to requests from trading partners to confirm that a particular product identifier, including the standardized numerical identifier (SNI), on the product that is the subject of the request corresponds to the product identifier that was affixed to or imprinted upon that product by the manufacturer of that product.\*

\*Verification Systems under the Drug Supply Chain and Security Act for Certain Drug Products, Guidance for Industry, March 2022

# Verification Under DSCSA - Regulatory and Business

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## Business Rules and Requirements: Flexibility for VRS Responders to set their own rules

- Error messaging can be general or detailed
- Expiration Date: Day may be included or excluded
- Responders may determine what qualifies a product as illegitimate or suspect
- Responders may determine if illegitimate or suspect status is shared
- Responders may determine if a recalled or expired product returns as valid or invalid



# What is a Verification Router Service?

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## Requestor

Creates and submits verification requests

Wholesale Distributor  
Dispenser



## Responder

Provides responses for specific GTINS

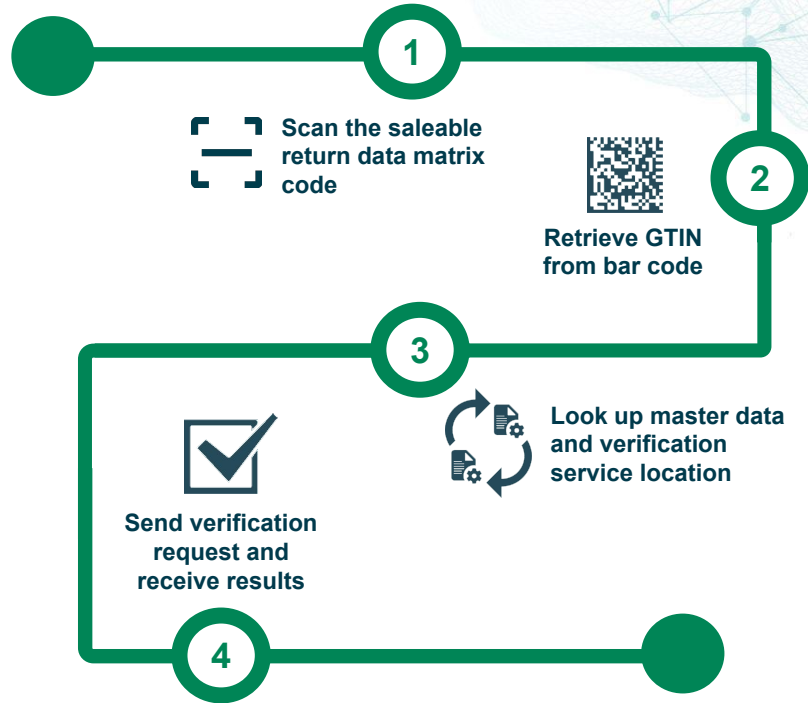
Manufacturer



## Lookup Directory

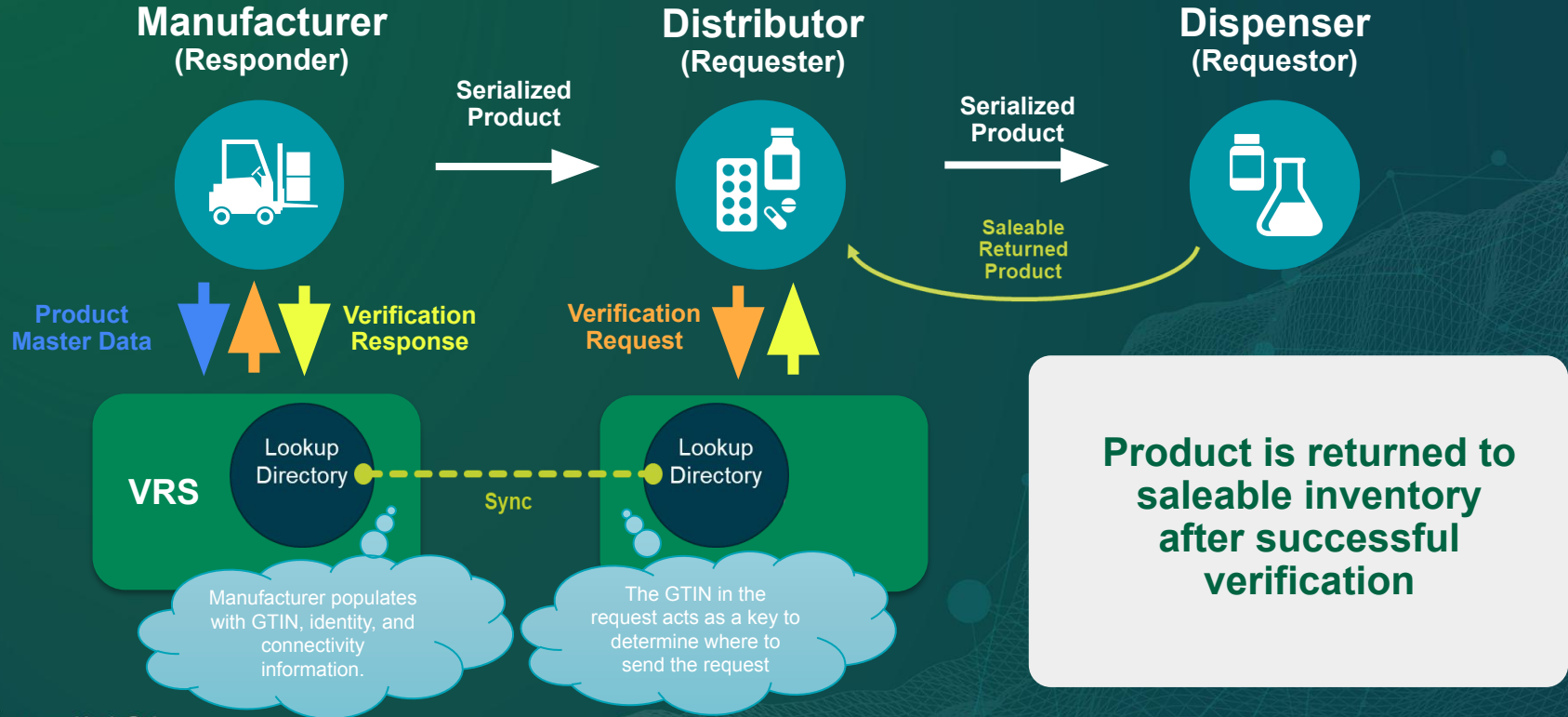
Operates as a phone book for GTINs, linking the requesting system to the right responder

# The Relationship Between Verification & Master Data



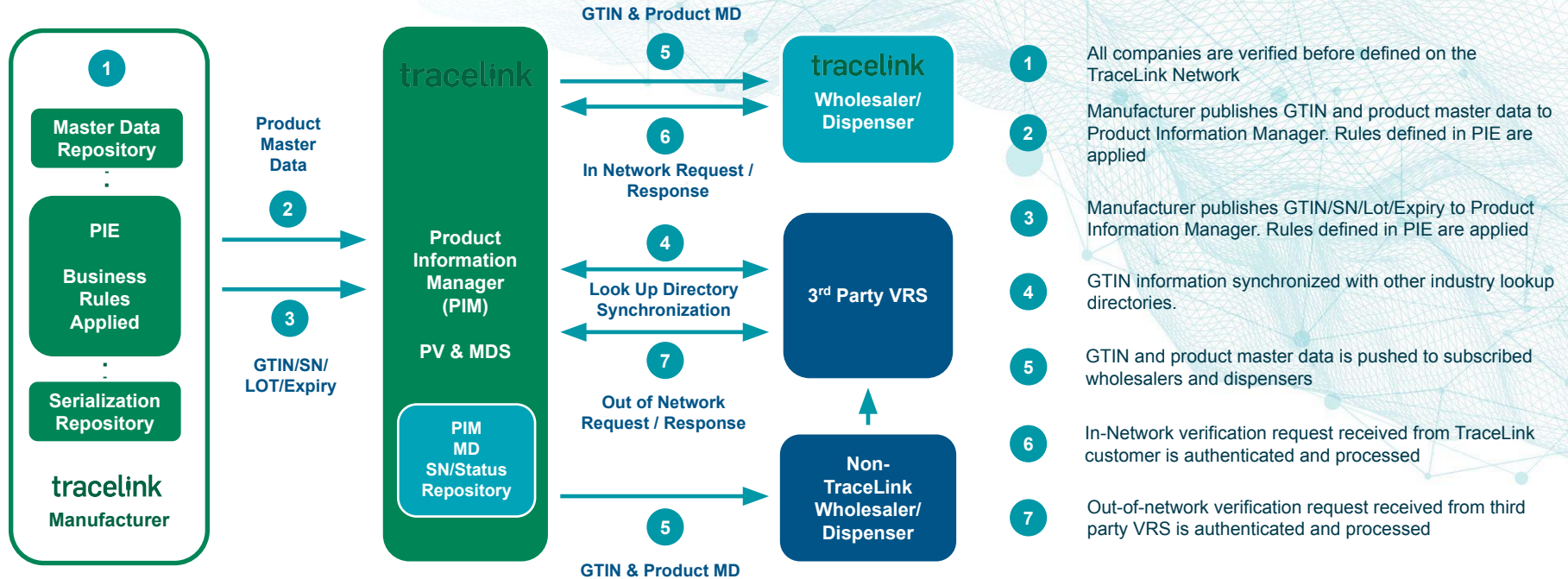
- Saleable returns verification will require access to product GTINs
- GTINs must be accurate to ensure proper lookups
- Incorrect or missing GTINs will result in wholesaler delays
- Manufacturers may receive wholesaler penalty fees for missing or inaccurate GTIN information

# Verification Router Service (VRS) Network Standard





# Product Information Manager Verification and Master Data Sharing

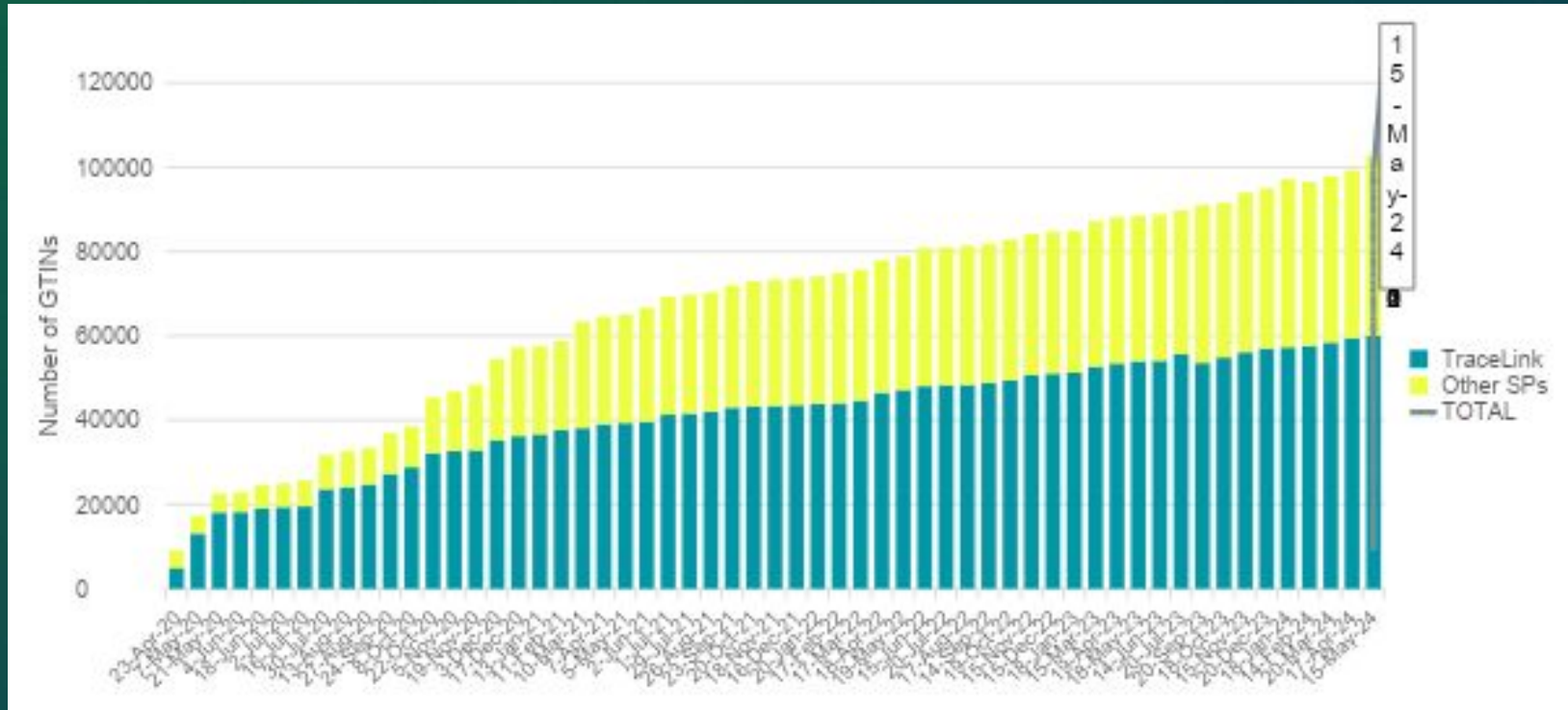


# Current Industry Status - VRS System

VRS Provider	Initial Interop Testing	ATP Testing	LVMS 1.3 Testing	Live with TraceLink
NABP (Formerly MediLedger)	Completed	Completed	Completed	Live
Cardinal Health	Completed (through MediLedger)	Completed	Completed	Live
SAP	Completed (through MediLedger)	Completed	Completed	Live
Systemech	Completed (through MediLedger)	Completed	Completed	Live
TraceKey	Completed (through MediLedger)	No Participation	No Participation	Live
Gateway Checker	Completed	Completed	Completed	N/A
Jekson Vision	Completed	Completed	Completed	Live
LSPedia	Completed	No Participation	Completed	Live
Axway	Completed (through LSPedia)	No Participation	No Participation	Live
Movilitas	Completed (through MediLedger)	Completed (through MediLedger)	Completed (Direct)	Live
Optel/Verify Brand	Completed (through MediLedger)	No Participation	Completed (Direct)	Live
rfXcel	Completed	Completed	Completed	Live
TraceLink	Completed	Completed	Completed	N/A
Adents	Completed	No Participation	No Participation	INACTIVE - under rfXcel
Dot Med	Completed	No Participation	No Participation	Live
TrackTraceRx	Completed	No Participation	No Participation	Live
Authentag: Track One	Completed	No Participation	No Participation	Not Engaged
Navitas	Completed	No Participation	No Participation	Not Engaged
Covectra	Completed	No Participation	No Participation	Not Engaged



# Current Industry Status - VRS System



# Current Industry Status - Industry Support

## Industry Updated to GS1 Lightweight Verification Messaging Standard R1.3

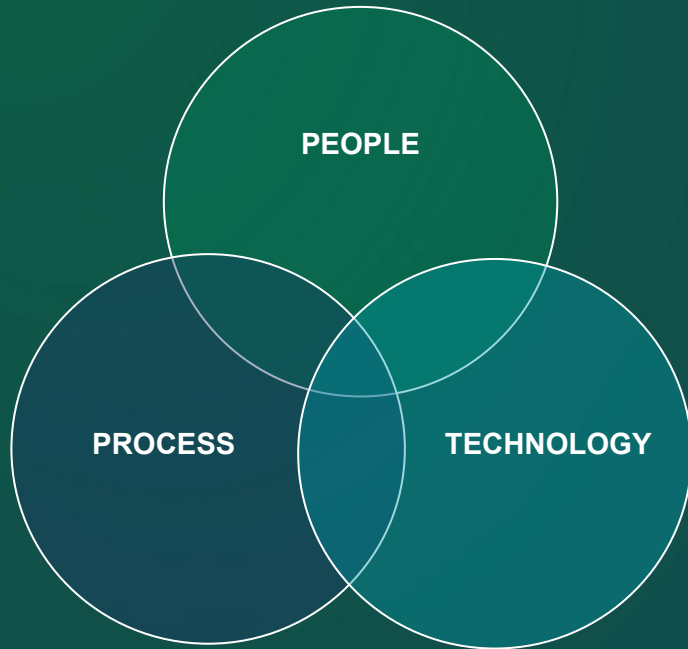
- Extended expiry and illegitimate status added as an additional information field
- Possession requirement enforced for requestors
- Verification context field added for requestors to indicate reason for the request
- Contact information required in all requests and responses

Over 50 test cases developed and executed between TraceLink and other VRS providers to ensure functionality is fully interoperable prior to release in July 2023

Interoperability Test Plan R1.3 (Total # of Test Cases: 54)						
Requestor Test Case Number	Category	Comment	Corresponding Responder Test Case Number	Test Case Name	Test Objective	Expected Behavior
BLS Test Case						
VRS_03_10	R11 Test Case		VRS_M_10	RRL_PL_match_mpl_mpl_mpl PI Verification Response Scenario A1	Verify that a properly formed verification request is successfully processed by the VRS responder Be able to respond to a verification request for scenario A1	VRS requester sends PI test data simulating where the product is for sale. VRS Request includes offPossession + true, requester's contact email and telephone are provided, context + GlobalSustainable, header includes GSUS-Version + 1.3.0 VRS responder returns a verified true with blank additionalInfo and verification ofManufacture in blank and responder's contactPoint email and telephone. PI Response header includes GSUS-Version + 1.3.0
VRS_03_20	R11 Test Case		VRS_M_20.1	RRL_PL_match_revokeL_mpl PI Verification Response Scenario B1	Be able to respond to a verification request for scenario B1 with revoked as additionalInfo	VRS responder chooses to return a verified true response and provides "Revoked" as additionalInfo and responder's contactPoint email and telephone. PI Response header includes GSUS-Version + 1.3.0 VRS requester sends PI test data simulating where the product is recalled with true. VRS Request includes offPossession + true, requester's contact email and telephone are provided, context + GlobalSustainable, header includes GSUS-Version + 1.3.0
VRS_03_21	R11 Test Case		VRS_M_21	RRL_PL_match_expired_mpl PI Verification Response Scenario B1	Be able to respond to a verification request for scenario B1 with expired as additionalInfo	VRS responder chooses to return a verified true response and provides "Expired" as additionalInfo and responder's contactPoint email and telephone. PI Response header includes GSUS-Version + 1.3.0 VRS requester sends PI test data simulating where the product is expired with true. VRS Request includes offPossession + true, requester's contact email and telephone are provided, context + GlobalSustainable, header includes GSUS-Version + 1.3.0
VRS_03_22	R11 Test Case		VRS_M_22	RRL_PL_match_revokeL_false PI Verification Response Scenario B2	Be able to respond to a verification request for scenario B2 with verification ofManufacture_policy and revoked as additionalInfo	VRS responder chooses to return a false verification response and provides "Revoked" as additionalInfo and verification ofManufacture_policy. PI Response header includes GSUS-Version + 1.3.0 VRS requester sends PI test data simulating where the product is recalled with false. VRS Request includes offPossession + true, requester's contact email and telephone are provided, context + GlobalSustainable, header includes GSUS-Version + 1.3.0
VRS_03_23	R11 Test Case		VRS_M_23	RRL_PL_match_expired_false PI Verification Response Scenario B2	Be able to respond to a verification request for scenario B2 with verification ofManufacture_policy and expired as additionalInfo	VRS responder chooses to return a false verification response, provides "Expired" as additionalInfo and verification ofManufacture_policy. PI Response header includes GSUS-Version + 1.3.0 VRS requester sends PI test data simulating where the product is expired with false. VRS Request includes offPossession + true, requester's contact email and telephone are provided, context + GlobalSustainable, header includes GSUS-Version + 1.3.0
VRS_03_30	R11 Test Case		VRS_M_30.1	RRL_PL_match_support PI Verification Response Scenario C1	Be able to respond to a verification request for scenario C1	VRS responder returns a false verification response, provides additionalInfo "Support" and verification ofManufacture in "Not_SupporableItem" and responder's contactPoint email and telephone. PI Response header includes GSUS-Version + 1.3.0

# Key Learnings

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## PEOPLE

- Collaboration is key!
- Feedback, feedback and more feedback!
- Stay informed on changes

## Standards

- Workgroups are key!
- Everyone must be on the same version
- Little room for differences in interpretation

## TECHNOLOGY

- Verification Router Service (VRS)
- Authorized Trade Partner (ATP) Credentials
- Master Data Exchange



# Recommendations

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## No Verification Network

- Review business processes for how to handle verifications
- Ensure you have the staff to support such requests
- Look at implementing a VRS system



## Has Verification Network

- Ensure VRS has been tested and is live
- Ensure staff is trained on how to handle verifications
  - Failed and Successful
- Create SOPs for when verifications are performed

# Questions?

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