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

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Verification Under DSCSA - Regulatory and Business

2D

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 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

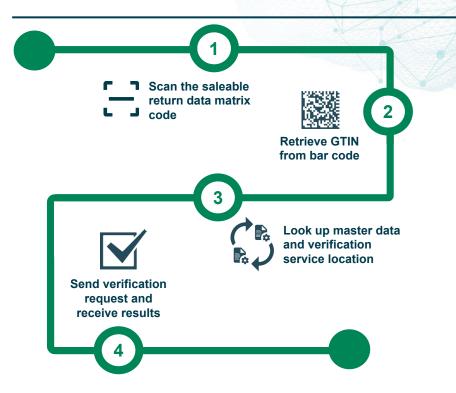
Business Rules and Requirements: Flexibility for VRS Responders to set their own rules

- 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?

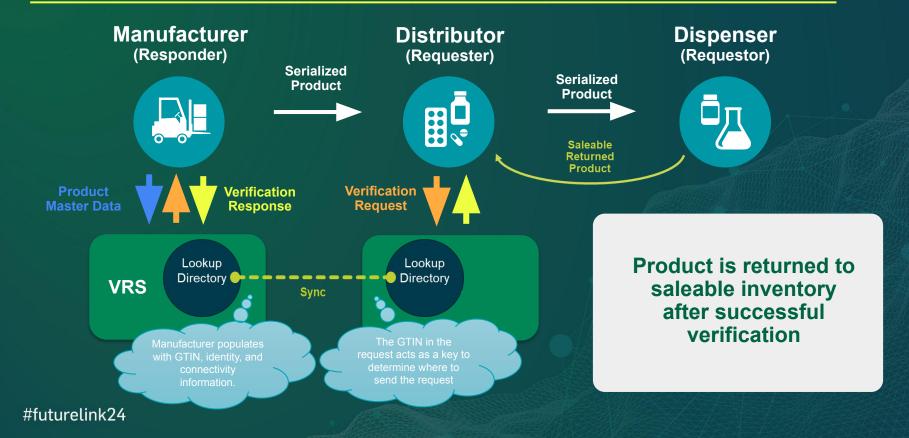


The Relationship Between Verification & Master Data

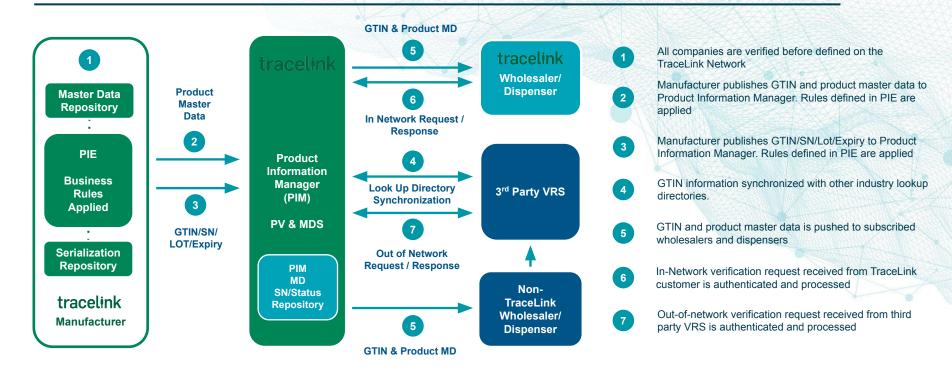


- Saleable returns verification will require access to product GTINs
- GTINs must be accurate to ensure proper lookups
- Incorrect or missing GTINs will result in wholesaler delays
- Manufacturers may receive wholesaler penalty fees for missing or inaccurate GTIN information

Verification Router Service (VRS) Network Standard



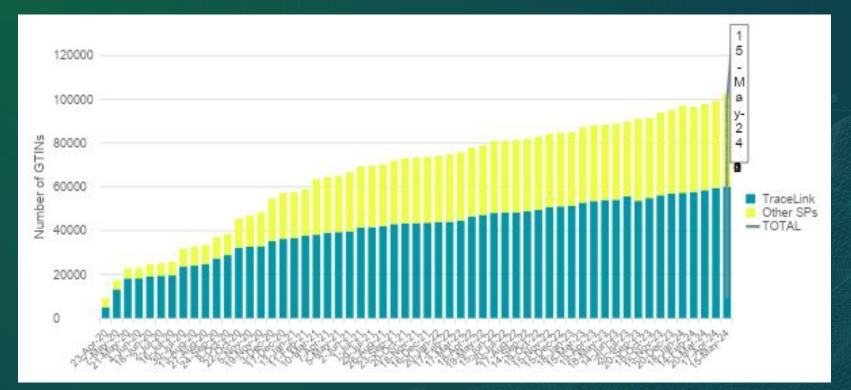
Product Information Manager Verification and Master Data Sharing



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
Systech	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

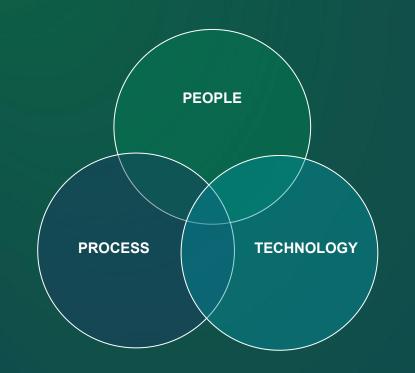
Industry Updated to GS1 Lightweight Verification Messaging Standard R1.3

- Extended expiry and illegitimate status added as an additional information field
- Possession requirement enforced for requestors
- Verification context field added for requesters 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 R1.1 Test Cases	Category	Comment	Corresponding Responder Test Case Number	Test Case Name nJ. J. trest cases executed with context-obcasale accessed um,	Test Objective	Expected Behavior			
VR5_03_10	R11Test Case			R&R_PL_match_no_uvR_info: P! Verification Response Scenario A1	Verfy that a properly formed verification request is successfully processed by the VHS responder Be able to respond to a verification request for scenario A1	VIGI expansion and Pitter data simulating when the product in its raik VIGI Request holds of officiality of the simulation of the product of the simulation of the provided content - discussible black of the simulation CSUSI-Viewson - 13.00 VIGI sequencies must avail include with black additionable and emission of black the same a black and responder's contract/black emission and telephone. If Response header includers GSUSI-Viewsin - 13.00			
VR5_03_20	R11Test Case			R&R_PL_match_recalled_true PI Verification Response Scenario B1	Be able to respondro a verification request for scenario B1 with recalled as additionalinfo	WG expansion candpillere data simularing viewe integroducto recalidativitudiam. WG Requestribuidos of Possessitir 1-tus, requestor's contacter canal and telephone are provided, conter- "directabilitativitudinaming and includer GSUS Version 11.00 (95) especial contacts in units a verticabilitativitudinaming and and the additionality of a segment of a verticability of a segment of another the additionality of a segment of a verticability of a segment of a verticability of a additionality of a segment of a verticability of a segment of a segment of a additionality of a segment of a segment of a segment of a segment of a segment of a segment of a segment of a segment of a segment of a additionality of a segment of a segment of a segment of a segment of a segment of a segment of a segment of a segment of a segment of a segment of a segment of a segment of a segment of a segment of a segment of a segment of a segment of a segment of			
VR5_03_21	R11Test Case			R&R_PL_match_expled_mue PI Verification Response Scenario B1	Be able to respond to a verification request for scenario BT with expired as additionalistic	WS experts and Piter data sinularity an experipative. WS Repair Industry environmental experiments and an experimental experimental experimental comment discussion behavior in the experiment of the sinular to 2015. Version 11.30 (19) responder concerns in term an environmental and references and additionality and responder's contactPoint small and telephone. PResponse handler industry SIS Version 11.30			
VR5_03_22	R11Test Case			R&R_PL_match_recalled_Ialse PI Verification Response Scenario B2	Be able to respond to a verification request for scenario B2 with verification?#ableHearch of Manufacturer_policy and <u>resulted</u> as addisonalizio	WB sequence cards Piter data sinularity where the products in called WH-dam. WB Request holds or Plenserskin + hus, generative's consistent and and belefihone are provided, content - thoras Salesbelt/Renum, Neader Includer (SSUEV-Version 11.00 (SS) sequencide concerts team in alice evolution reconcert enclosed to "Research" and addressible and vertice score BalenBason in Marchanner, policy and respondent - addressible and vertice score BalenBason in Marchanner, policy / with respondent - scontace/Point enal and telephaner. Phenotone header to holder (SSUEV-Version - 100 - Piter Participant - Piter Participant - Piter Participant - addressible vertice score BalenBason in Marchanner, policy / and respondent - scontace/Point enal and telephaner. Phenotone header holder (SSUEV-Version - team) - team - scottace and the score of the provide score to holder (SSUEV-Version - team) - scottace and the score of the provide score of the provide score to holder (SSUEV-Version - to the provide score of the provide score o			
VR5_03_23	R11Test Case			P&R_PL_match_explored_false PI Verification Response Scenario B2	Be able to respond to a verification request for scenario B2 with verifications able Reason of Manufacture_policy and <u>applied</u> as addisonalize	VHS requests and Piter data incluing view legodate a neglegible. VHS Request halds of Dissessifier 1 and sequentiar's consistent and and belefihone are provided, content "docadslike/biferum", hadde includer CSTUP Version 11.00 VHS responder docade to ream a hist evolution response provider. Tip lateful at addressifier and and relegibless Piterprove hadders and belog SV Version 11.00 contract/biter and and relegibless. Piterprove hadders addressifier 1 and addressifier and and relegibless. Piterprove hadders addressifier 100 Version 1 contact/biter and and relegibless. Piterprove hadders addressifier 100 Version 1 version 100 Version 1			
VR5_03_30	Rt1TestCase			R&R_PL_match_sourpect PI Verification Response Scenario C1	Be able to respond to a swiftcation request for scenario C1	USS requestors and off her data including when the product is notice. WSS Request includes of the next in the requestance is constant e and all and telephone are provided, content in documents, header includes (SSUS-Version 13.0° USS reproduct means a false welf-station encourse, product additionable "daggers" and efficients' additionations in the Linguistic means and the elephone. PReprint and enal and telephone. PReprint header includes (SSUS-Version 13.0°			

Key Learnings



#futurelink24

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



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?

