

2024 Traceability Webinar Series

VRS: An Overview and Update on VRS Improvements

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Before we get started...

- Today's webinar is being recorded.
- All participant lines are muted.
- Today's presentation and recording will be available by ***Wednesday, July 17th***.

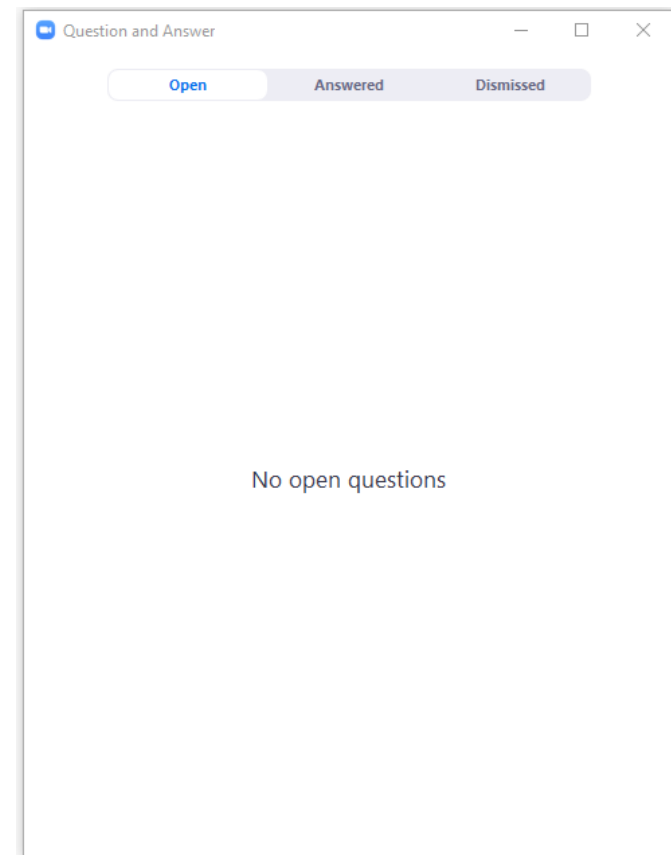
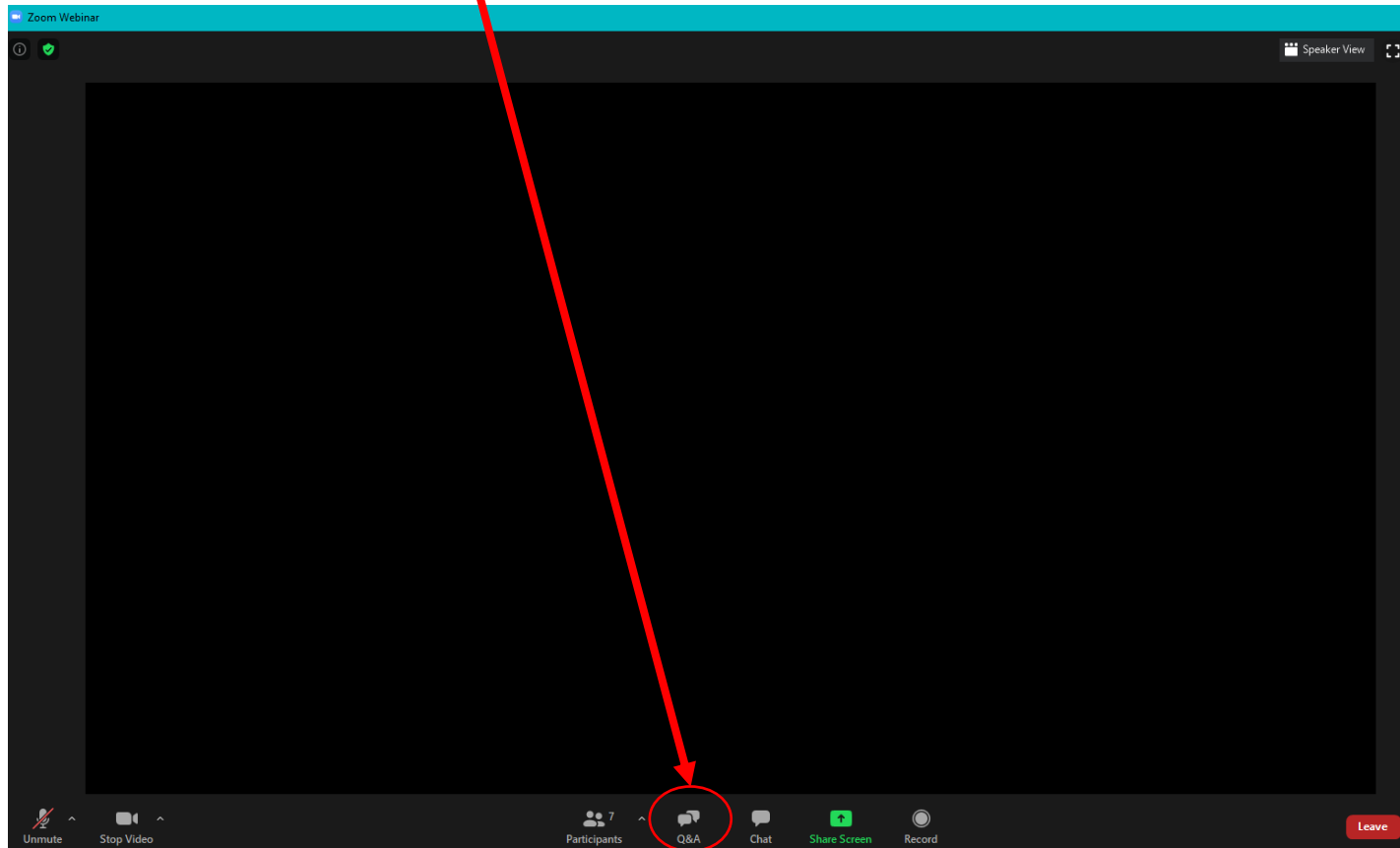
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Questions & Answers

Click the Q&A bottom Zoom menu to open



Panel

Craig Little, Senior Systems Developer, Value Drug Company

Justin Macy, Director of Innovation, National Association of Boards of Pharmacy®

Maryann Nelson, Regulatory Manager, Cardinal Health, Inc.

Elizabeth Waldorf, Director, Global Traceability and Standards,
TraceLink Inc.

Moderator: Jaidalyn Rand, Director, Industry Relations, Healthcare
Distribution Alliance

***What is VRS & Why is it
Important?***

Verification as defined in DSCSA

DSCSA Section 581(28)

“The term “**verification**” or “**verify**” means determining whether the **product identifier** affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager, as applicable ...”

DSCSA Section 582(b)(4)(C)

“upon receiving a request for **verification** from an *authorized* repackager, wholesale distributor, or dispenser **that is in possession or control of a product** ... a manufacturer shall, not later than 24 hours after receiving the request for verification or in other such reasonable time as determined by the Secretary, based on the circumstances of the request, notify the person making the request **whether the product identifier, including the standardized numerical identifier, that is the subject of the request corresponds to the product identifier affixed or imprinted by the manufacturer.**”



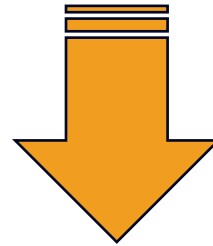
Verification Router Service (VRS)

VRS is an interoperable implementation of DSCSA verification requirements according to industry standards



VRS Evolution

In 2017, VRS was originally designed for saleable return product verification. Responder can provide additional information to indicate if a product is recalled, suspect, or expired.



Starting July 2023

Additional Contexts

- Suspect or Illegitimate Product Investigation
- Exceptions Processing
- Status Check

Requester Attestation

- Possession or Control

Expanded Addt'l Info

- Extended Expiration
- Added Illegitimate to "Not for Distribution" Response

Contact Info

- Include Email or Phone for Requester & Responder

Opportunities for Adoption

Forecast of what's to come?

➤ Leverage of existing functionality

- Support suspect product investigations as a primary purpose.
- New/Additional stakeholder (e.g., dispensers and regulators).
- Broader adoption generally as enforcement deadlines approach.
- VRS used for to replace or support other DSCSA processes.

➤ Expansion of use cases, but existing infrastructure.



Future Expectations

Manufacturer Trends

- Improved response accuracy due to integration with reverse-logistics providers to provide updates on destroyed medicines

Distributor Trends

- Existing saleable returns verification use reduced due to replicant data.
- Product verification status check at time of receipt and prior to fulfillment to verify supply integrity, primarily by secondary distributors.



Future Expectations

Dispenser Trends

- Increased interest in using VRS as an additional level of product verification when triaging data exceptions to ensure patient safety.
- Enables dispensers to meet compliance requirement during suspect product investigation to verify product identifiers on at least 3 packages or 10% of such suspect product.
- Assist in confirming appropriate product usage with extended expiration dates and recall information.

Regulator Trends

- Early interest from state boards:(1) as part of an investigation and (2) to find manufacturer contact information.

Adoption

For greater adoption to be successful, the community needs to focus on education and outreach.

- Existing VRS stakeholders will need to anticipate these new use cases in their configurations.
- Future VRS stakeholders will need to understand the existing scope of VRS and what it can and can't accomplish.

Collaboration with Stakeholders

DSCSA Saleable Returns Requirement

- **DSCSA requires wholesale distributors to verify the product identifier before re-distributing a saleable returned product**
- **Direct to replicate** - Manufacturers send serialized data with each shipment to wholesale distributors
 - WD store GTIN, Serial #, Lot, and Exp. Date in local repository and use it to verify product identifiers internally
- **Direct to source - Verification Router Service (VRS)**
 - Manufacturers maintain their database of serial numbers and subscribe to routing service that brokers all WD requests for verification and corresponding manufacturer responses

Wholesale Distributor Saleable Returns Process

- Returns processor in Distribution Center scans 2D barcode on package



- Response Received - Code 200
 - Verified True – Product placed in salable inventory
 - Verified False – Quarantine product and reach out to manufacturer to confirm
- Error Response e.g., 404 No GTIN Found/502 Bad Gateway
 - November 2024 – Quarantine and contact vendor manually with verification request

Verification Request Sample – Cardinal Health

(one location)

Response Received

Month	Total Verifications	Response Code 200	Percent Responses received	Verified True	% Verified True	Verified False	% Verified False
April	14,292	9,548	67%	8,758	92%	790	8%
May	21,303	14,568	68%	13,447	92%	1,121	8%
June	18,440	11,478	62%	10,619	93%	859	7%

Error Response

Month	Bad Request 400	Unauthorized 401	Forbidden 403	GTIN Not Found 404	% GTIN Not Found
April	19	39	19	3,175	22%
May	21	28	12	4,691	22%
June	342	5	12	3,910	21%

Month	Internal Server Error 500	Service Unavailable 503	Bad Gateway 502	% Bad Gateway
April	38	67	1,387	10%
May	189	51	1,743	8%
June	286	18	2,389	13%

VRS Provider Network Provides an Opportunity to Share Issues and Collaborate on Best Practices

- “Error Response” rate of 35% is concerning
 - Could be due to GTINs not being loaded in the lookup directory, requests not formatted correctly, server unavailable or manufacturers not participating in the VRS
 - Manufacturers missing out on opportunities to identify potential issues with their serialized data
 - Additional staff will be needed to handle these verifications manually come November
- No illegitimate product was identified
 - All initial negative responses are subsequently verified
 - “False Negatives” result in wasted time and resources for both for Distributors and Manufacturers
- Scanners aren’t perfect
 - Caps Lock on can invert alpha characters from upper case to lower case on Lot and Expiry
 - Additional characters sometimes inadvertently added to fields
- Latency issues may cause processing delays
 - Some requests happen in sub-seconds while others take much longer
 - Performance Test Scripts Updated

Benefits of Governance

Increased Cohesion Among SPs & End-User Input

➤ Participants are committed and will continue to improve the VRS Solution through:

- New Policies & Best Practices documents to resolve errors and increase alignment to root out ambiguity
- Executed Active Records Syncing and established schedule for future activities
- LD Technical Specifications revisions that leads to reduced variability in implementation process
- Updated Performance Test Scripts for assessing potential latency issues
- End-user input that drives policy development and help prioritize areas of improvement

Upcoming Events

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.

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