



Louisiana Board of Drug and Device Distributors

VR-DAY Verification Readiness Exercise November 19, 2024

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George Lovechio, Executive Director
Victoria Bienvenu, PharmD, Compliance Manager

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Introduction

Enacted in 2013, the [Drug Supply Chain Security Act \(DSCSA\)](#) is a U.S. federal law designed to enhance the security and integrity of the pharmaceutical supply chain, thereby protecting patients from counterfeit, contaminated, or otherwise harmful drugs. The law establishes a framework for tracking and tracing prescription medications throughout the supply chain. It requires manufacturers, repackagers, distributors, third-party logistics providers, and dispensers to share transaction data, maintain product traceability, and implement product identifier verification processes to authenticate drug legitimacy. It also allows for access by authorities including federal and state regulators.

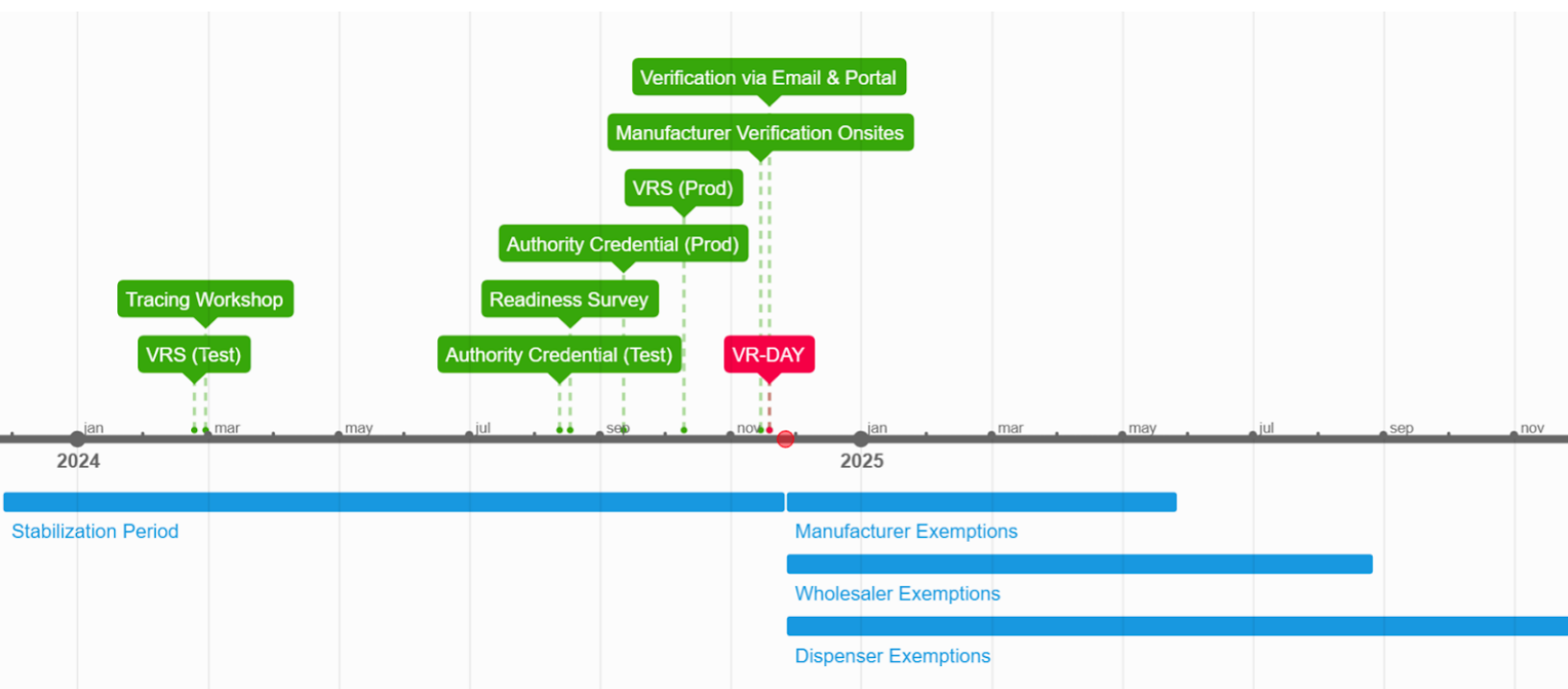
The mission of the Louisiana Board of Drug and Device Distributors (the Board) is to safeguard life and health and to promote public welfare of all citizens by the licensing and regulation of entities engaging in the distribution of legend drugs or legend devices within and into the state of Louisiana. Part of the Board’s mandate is to ensure that licensees establish, maintain, and adhere to a number of written policies and procedures that align with the requirements of the DSCSA. To support this mission, the Board intends to make use of the enhanced drug distribution security (EDDS) network under the DSCSA as per §203. In addition to enhancing patient safety, these efforts also serve to protect brand integrity, so all legitimate parties are aligned to work together.

Interoperability under the DSCSA can only be accomplished through collaborative effort. To evaluate these capabilities in a real-world setting, the Board conducted Verification Readiness (VR) Day – an industry readiness exercise to provide DSCSA stakeholders including the Board a safe space to undertake a real-time series of product verifications and observe the results, while preserving stakeholder anonymity as much as possible.

Background

Under the DSCSA, Authorized Trading Partners (ATPs) in the pharmaceutical supply chain are required to exchange product compliance information, including drug verification and tracing data. These exchanges of information often take place between “indirect” trading partners with no prior business relationship and varying levels of sophistication, as well as between trading partners and state and federal authorities. This is especially important in the course of suspect and illegitimate product investigations, when authorities may need to quickly reach the appropriate point of contact.

While many DSCSA requirements (including product identifiers and ATP confirmation) are already in effect, the full set of DSCSA requirements comes into effect this month with the end of the [FDA stabilization period](#) apart from [exemptions for connected trading partners](#). Over the course of 2024, the Board has been active in advancing the use of the EDDS to enable more effective inspections and empower trading partners to more easily respond to routine requests. This included an industry tracing exercise, Readiness Survey, and the VR-Day Exercise.



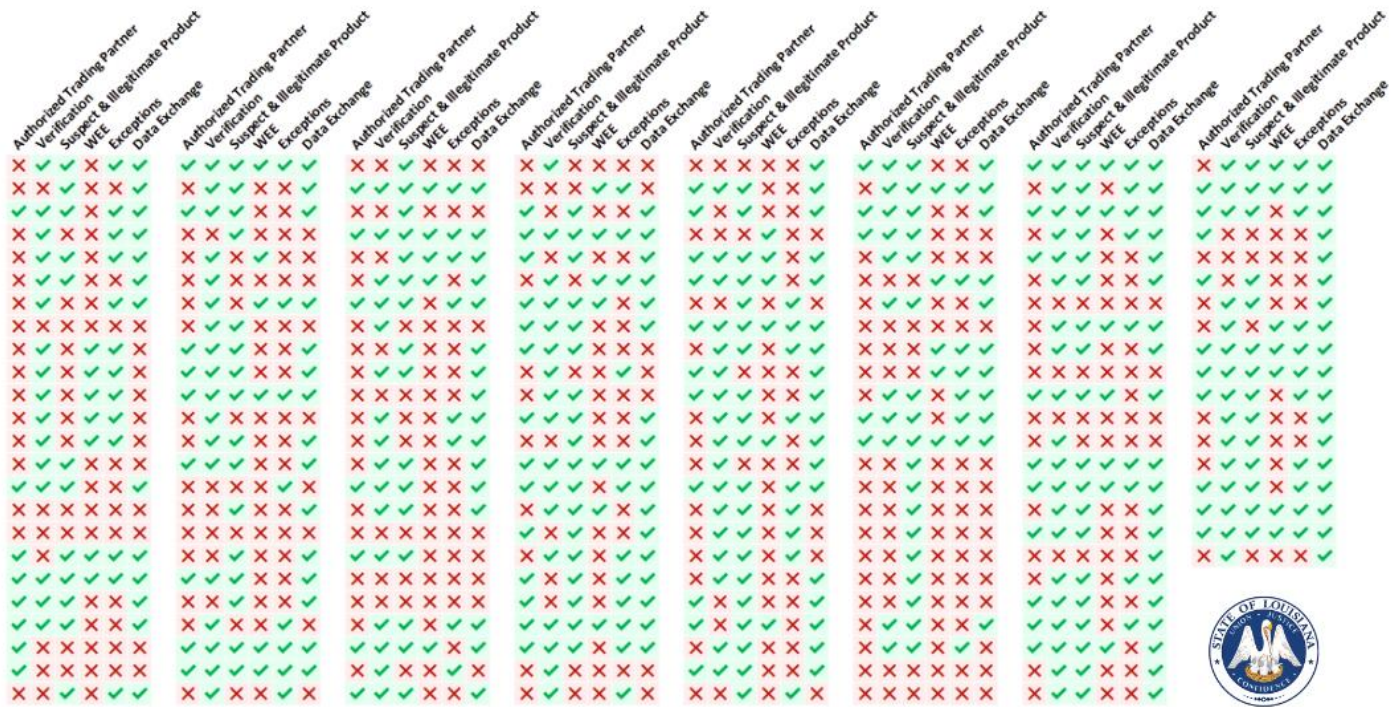
DSCSA Tracing

Under Section 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), DSCSA enhanced drug distribution security requirements, trading partners must meet the following requirements:

(D) The systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required.

Policies & Procedures

As part of this effort, the Board requested that trading partners provide their DSCSA policies and procedures ahead of upcoming license reviews and inspections. The graphic below illustrates a representative sample of DSCSA policy & procedure coverage. Each row of six represents the document(s) submitted by a single facility.



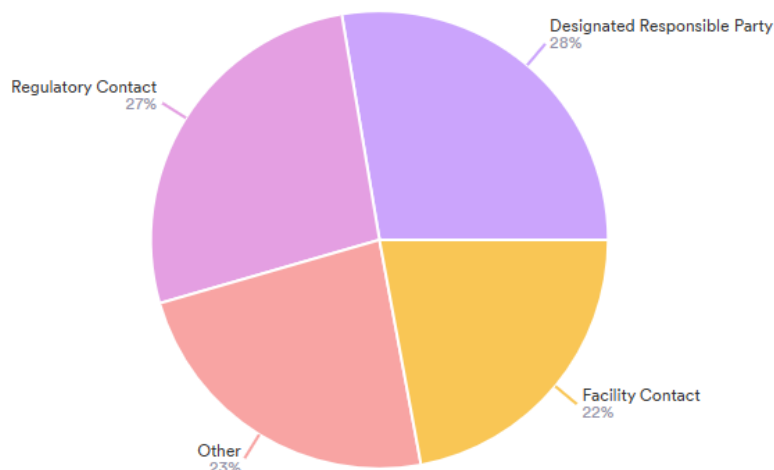
On a per-facility basis, the policies and procedures reviewed by the Board reveal the following coverage of key DSCSA compliance topics:

- 77% of respondents cover Suspect & Illegitimate Product
- 75% cover Product Identifier Verification
- 74% cover Data Exchange (e.g. EPCIS, T2/T3)
- 45% cover Exceptions (e.g. Missing Data)
- 43% cover Authorized Trading Partners (ATPs)
- 29% cover Waivers, Exemptions & Exceptions (WEEs)

DSCSA Points of Contact

As the issuing body for all manufacturers and wholesalers selling or shipping into the state of Louisiana, the board has multiple touchpoints for each licensed facility, including a designated responsible person, facility contact, and regulatory contact. During the course of the Readiness Survey, the board asked licensees to indicate their preferred contact for suspect or legitimate product investigations. Notably, there was a relatively even split among the three contacts, as well as nearly a quarter of all facilities identifying a fourth preferred point of contact for DSCSA-related inquiries.

Who should the State contact in the event of a suspect or illegitimate product investigation?



The full report can be found at <https://regulator.id/la/readiness-survey>.

DSCSA Product Verification

Under the DSCSA enhanced drug distribution security requirements, trading partners must have “systems and processes for verification of product at the package level, including the standardized numerical identifier.” This often involves a downstream trading partner such as a wholesaler or dispenser sending the request to the manufacturer or repackager responsible for the product identifier – the NDC, serial number, lot, and expiry date required to be on human prescription drug packages by the DSCSA. (More details about these requirements can be found on the [FDA's website](#).)

Introduction to Verification Router Service (VRS)

To enable interoperable product verification, a major component of the EDDS is the Verification Router Service (VRS), an industry-sponsored network of solution provider systems designed to automate verification requests and responses. The VRS enables verification of product identifiers for suspect or illegitimate product investigations, exception processing, status checks and saleable returns. While the use of the VRS is not mandated by law, many trading partners make use of the network due to business and operational efficiencies. The Board intends to leverage these capabilities in support of its efforts to keep patients safe from contraband drugs.

During the VR-Day Interoperability Exercise, the Board welcomed Ms. Jaidalyn Rand of the Healthcare Distribution Alliance (HDA), the organization hosting the VRS Provider Network. Ms. Rand covered the history of the VRS including its key development milestones since its inception:

- VRS Pilot & GS1 LVMS 1.0 (2018)
- VRS & ATP Credential FDA Pilots (2019)
- GS1 Lightweight Verification Messaging Standard (LVMS) 1.2 & Credential Testing (2022)
- GS1 LVMS 1.3 & Credential Production (2023)
- First Regulator on VRS (2024)

At a minimum, all VRS requests must consist of the following elements:

- the product identifier, i.e. the GTIN (which encompasses the NDC), serial number, lot, and expiry date;
- the GS1 Global Location Number (GLN) of the requesting party;
- the contact information of the requesting party, i.e. email address, phone number, or both;
- the context of the request, i.e. saleable return, suspect or illegitimate product investigation, exception verification, or status check; and
- whether the product is in the control or possession of the requesting party.

According to the GS1 LVMS Implementation Guideline, “initially, VRS implementations utilize Requestor and Responder Global Location Numbers (GLN)s for confirming ATP status. Subsequently, the pharmaceutical supply chain stakeholders added the verifiable ATP credential approach in demonstrating that a trading partner’s identity and authorized trading partner status have been digitally verified. Requestor and responder GLNs will continue to be a part of DSCSA verification requests and responses defined in this guideline, even when ATP verifiable credential is included.” While the use of verifiable credentials is not mandated by law, many trading partners choose to be digitally authenticated for operational efficiencies over the VRS.

More information about the VRS can be found on [HDA’s website](#), [PDG Blueprint Chapter 4](#), and in the [GS1 Implementation Guideline](#).

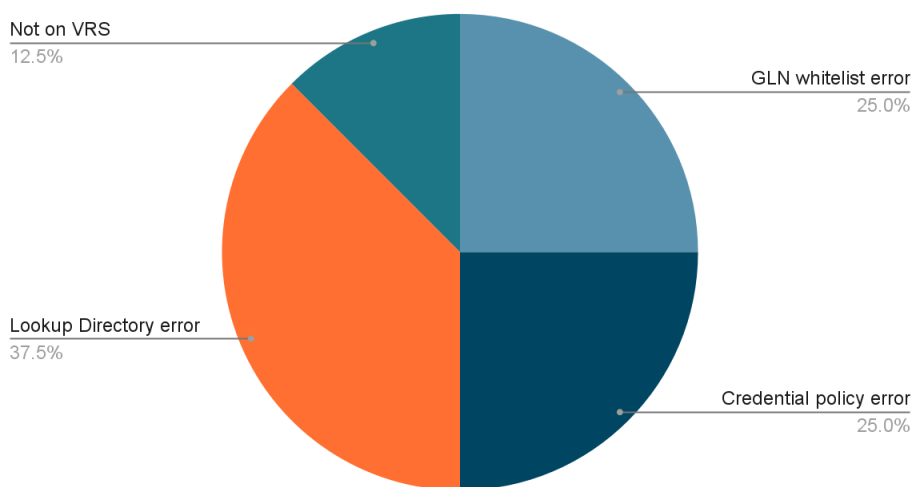
February 2024 Exercise

In February 2024, as part of the tracing exercise moderated by the Center for Supply Chain Studies under FDA observation, the Board first made use of the VRS testing service to evaluate its utility in support of suspect or illegitimate product investigations. The Board learned that by performing a verification request in advance of initiating a trace request, participants can nearly instantaneously confirm all-electronic contact information and gain quick insight into drug status.

October 2024 Exercise

On October 10, 2024, the Board conducted a limited exercise (n=8) with several manufacturers to gauge the effectiveness of the VRS verification in production.

Oct. 10, 2024 Exercise (n=8)



As shown in the chart above, 12.5% of requests were sent to manufacturer(s) not on the VRS, who were then asked to respond through a manual method. Of the other requests conducted, 25% blocked the request due to the Board’s

GS1 GLN being unrecognized, 25% were routed to manufacturers whose VRS provider(s) did not process the Board's Authority credential, and the remainder encountered issues with the VRS lookup directories. These results were reported to the trading partners and solution providers involved.

Although this first exercise in a production environment did not generate useful information about the drug packages in question, the fact that 7 of 8 packages generated a response motivated the Board to continue its efforts by scheduling a larger series of exercises, including VR-Day.

VR-Day Exercise

Introduction & Acknowledgements

The VR-Day Exercise was a multi-phase interoperable drug verification readiness exercise designed to provide DSCSA stakeholders, including the Board, an opportunity to perform real-time verifications and observe the results. This comprehensive exercise was conducted over the course of five days. The first day featured an inspection exercise focused on DSCSA verification requests and policies and procedures at two local Louisiana manufacturers, Sola Pharmaceuticals and Medecor Pharma. The final day culminated in a hybrid in-person and virtual event.

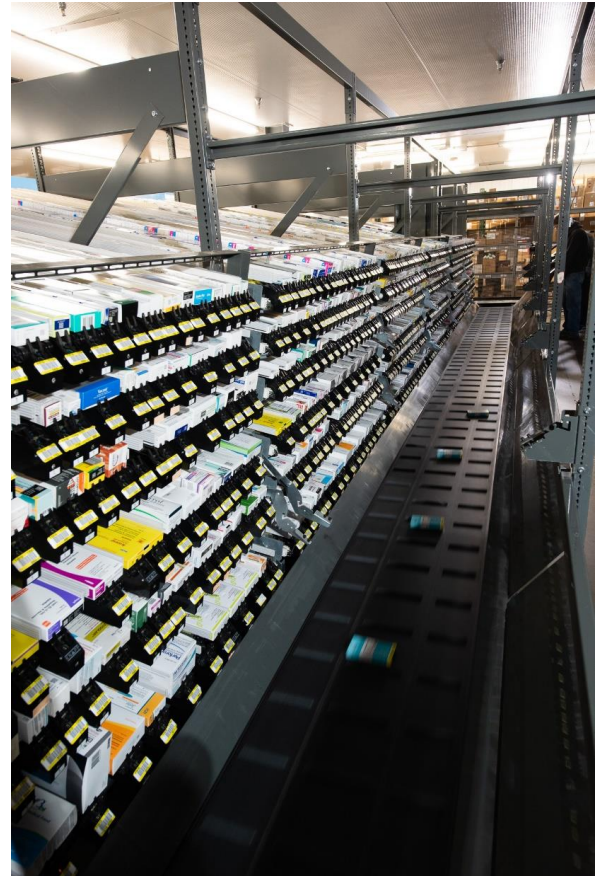
Special acknowledgments go to featured speakers George Lovechio, Executive Director at the Board; Victoria Bienvenu, Compliance Manager at the Board; and Jaidalyn Rand, Director, Industry Relations at Healthcare Distribution Alliance (HDA). The event was supported by Ben Taylor, Todd Barrett, Alex Colgan (LedgerDomain), and Marc Blekkink (Movilitas), with invaluable observations provided by NABP's onsite team.

We extend our sincere thanks to Keith LaNasa and Rebecca Risher from Sola Pharmaceuticals, and Lindsey Venable from Medecor Pharma, for their participation and cooperation during the Manufacturer Verification Request Day. Their contributions were instrumental in the success of the exercise. Special thanks also to Louisiana Wholesale and Morris & Dickson for hosting, as well as all who attended in person and virtually.

VR-Day Manufacturer Onsite Overview

Two manufacturers, Sola Pharmaceuticals and Medecor Pharma, participated in the Manufacturer Verification Request Day as part of the VR-Day Exercise. This initiative highlighted real-world DSCSA compliance practices, focusing on live verification requests and an inspection of each manufacturer's policies and procedures (P&P) specific to verification requests.

Sola Pharmaceuticals manufactures primarily generic prescription creams and eye drops, with 17 DSCSA-covered products. Their well-maintained P&P, available in both digital and physical formats, outlined essential definitions and compliance steps. Sola's staff demonstrated thorough knowledge of these procedures and had previously received and successfully handled two verification requests from a known distributor.





Medecor Pharma, which specializes in supplements and prenatal vitamins, has only one product that qualifies under DSCSA. This was their first experience with a verification request. Their P&P, developed from a solution provider template, provided a solid foundation but revealed the need for site-specific SOPs to better reflect their actual processes.

Both manufacturers currently choose to respond to verification requests manually via email, despite being set up for electronic verification. During the exercise, manufacturers received follow-up emails from the Board if the initial electronic requests were not acknowledged. These emails were routed to designated DSCSA contacts, who verified product identifiers and responded via a link contained in the original request. Manufacturer responses were recorded in the Board's portal as "verified" or "not verified."

The Board also reviewed each facility's P&P to ensure they:

- were specific to the steps taken at the facility;
- included clear time limits and roles for responding to requests; and
- addressed compliance with required DSCSA activities.

This exercise provided valuable insights into the practical implementation of verification requests and helped refine both manufacturers' and the Board's procedures. The collaboration demonstrated a shared commitment to enhancing compliance practices and ensuring patient safety.



"At SOLA Pharmaceuticals, patient safety is our priority. We're advancing procedures and verification systems to combat illegitimate drugs, ensuring every product is safe and of the highest quality. Collaborating with the Louisiana Board of Drug and Device Distributors and LedgerDomain, we're testing these enhancements in real-world scenarios to strengthen reliability."

– Rebecca Risher, SOLA Pharmaceuticals



Photos courtesy of Morris & Dickson, Louisiana Wholesale, Sola Meds, and Medecor.

VR-Day Interoperability Exercise

Parameter Development

HDA VRS Taskforce Review

Prior to the exercise, the Board reviewed its intentions with the VRS Taskforce hosted by HDA, soliciting feedback from HDA and solution providers to maximize learnings and minimize disruptions to members. It was agreed that the Board would confirm its control over the inventory and would mark each request as a “status check” but to simulate real world conditions, that manufacturers not be notified in advance. As part of the overall readiness exercise, the Board advised that the use of GLNs and credentials would be evaluated.

Manufacturer Selection

Prior to the exercise, the Board selected 60 leading manufacturers for the exercise to ensure a meaningful cross-section of manufacturers, based on likely inventories. Participating wholesalers then added in selected additional manufacturers that were material to their operations.

Inventory Selection

Participating wholesalers selected genuine drug packages prior to the exercise. In addition to ensuring that each manufacturer was represented, the wholesalers also ensured that:

- All products were human prescription drugs.
- No products were in shortage.
- No products were controlled substances.
- As few products as possible were subject to temperature controls.

Methodology

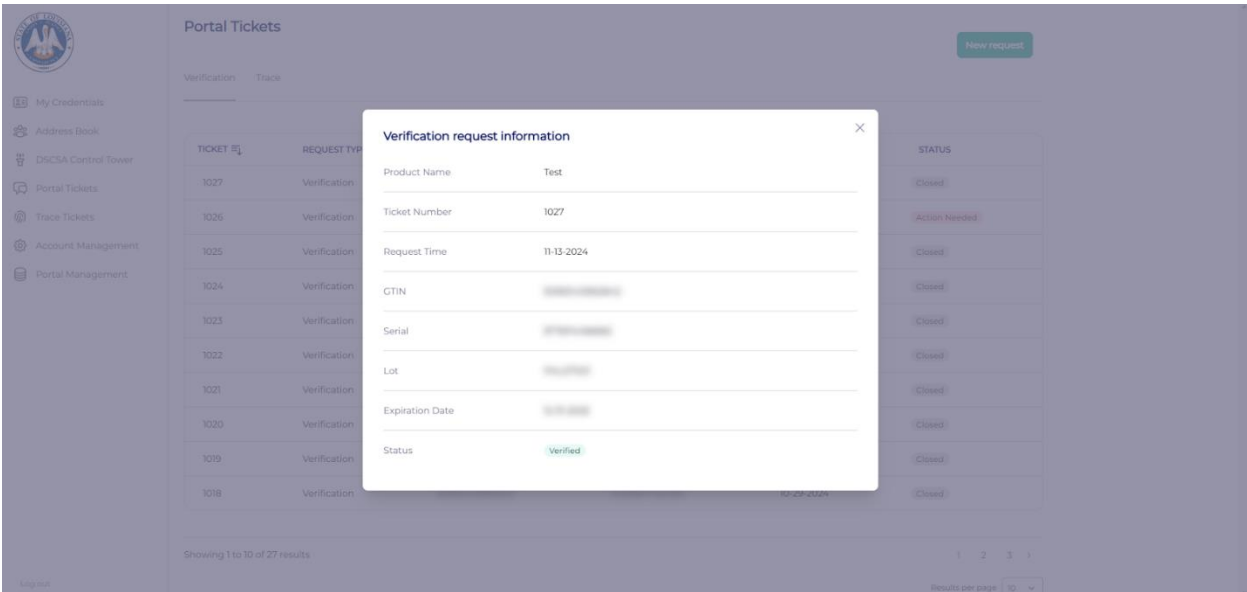
The objective of the VR-Day Interoperability Exercise is to assess the verification readiness of the VRS network involving different scenarios for GLNs and credentials. Four flights were conducted in all for this exercise, in consecutive order:

Flight	Requestor	GLN	Credential
1	Wholesaler 1	Wholesaler (Shared)	No
2	Wholesaler 1	Wholesaler (Shared)	Yes
3	Board	Board (Shared)	Yes
4 (Main)	Board	Board (Not Previously Shared)	No

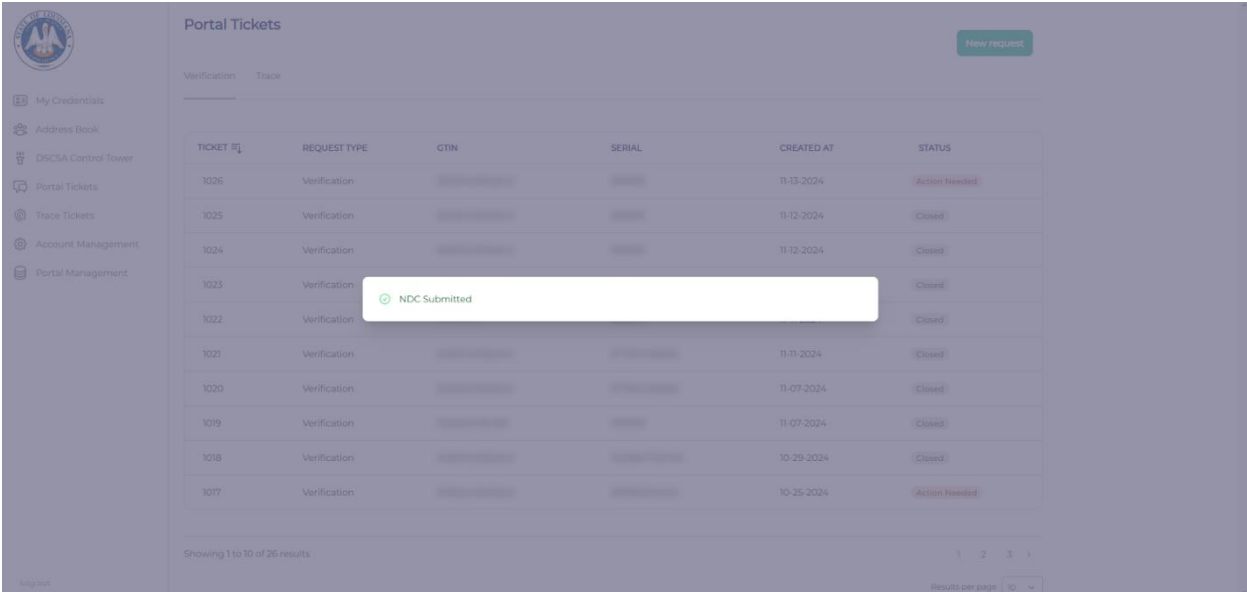
In all instances, verification requests were submitted with “DSCSA status check” and an attestation that the product was in the control or possession of the requesting party.

The outcomes for the verification testing were (1) VRS True, (2) VRS False, and (3) No Response.

In Flight 4, packages that had no responses from the VRS system were further investigated.



Automatic emails requesting responses via the Board's web portal were sent to points of contact on file.



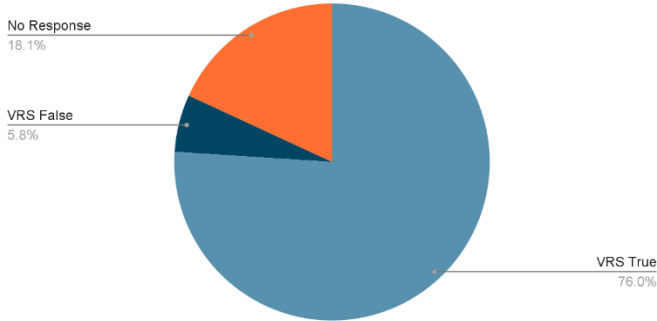
During the course of the exercise, all products were in possession or control of the Board. Products were held until all learnings from this exercise were cleared and the Board notified the participating wholesalers when packages could be re-introduced into the supply chain.

Product Verification Flight Results

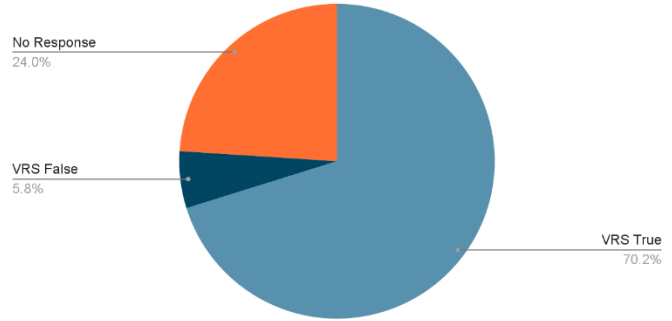
Flights 1 & 2: Wholesaler

One of the participating wholesalers (Wholesaler 1) sent two flights of verification requests via the VRS as a control. One flight used OCI-compliant ATP credentials, and one did not use credentials. In each flight, the same 171 saleable units were scanned, and the wholesaler’s GLN (which had been previously shared and was known to all their suppliers) was used.

Flight #1: Wholesaler (Uncredentialed, Previously Shared GLN, n=171)



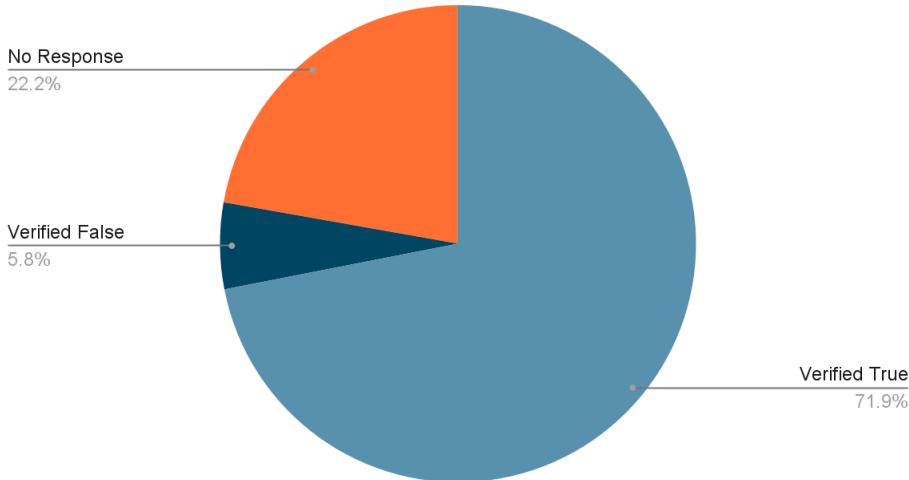
Flight #2: Wholesaler (Credentialed, Previously Shared GLN, n=171)



Flight 3: Board

The Board submitted a flight of credentialed requests using the Board’s OCI-compliant Authority credential and previously shared GLN. This involved the same inventory as the prior two flights.

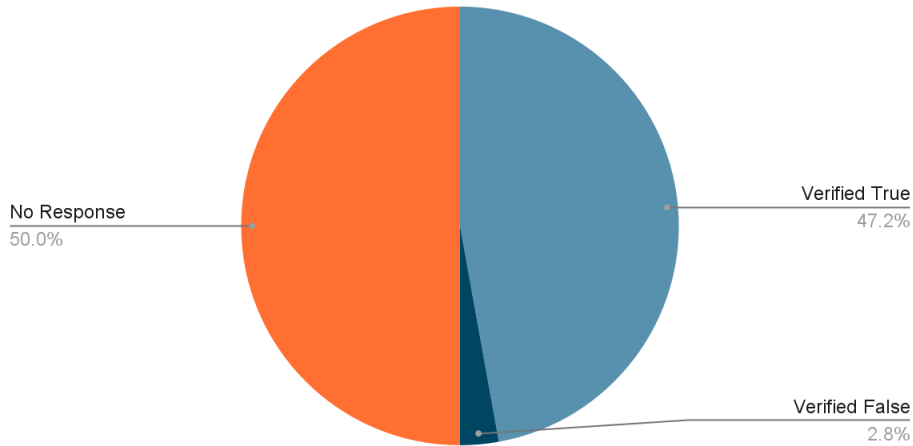
Flight #3: Board (Credentialed, Shared GLN, n=171)



Flight 4: Board (Main VR-Day Interoperability Exercise)

The main VR-Day Interoperability Exercise consisted of a single flight of verification requests from the inventory of both wholesalers (the original 171 from Wholesaler 1, and 5 from Wholesaler 2) totalling 176 packages submitted. For this flight, the Board made use of a GLN that had not previously been shared, in order to understand the potential impact of GLN “allow listing” policies on requestors. In this case, based on error reports received, nearly all of the packages that verified “true” in Flight 3 and did not verify in Flight 4 were the result of GLN-related rejections.

Flight #4: Board (Uncredentialed, Not Previously Shared GLN, n=176)



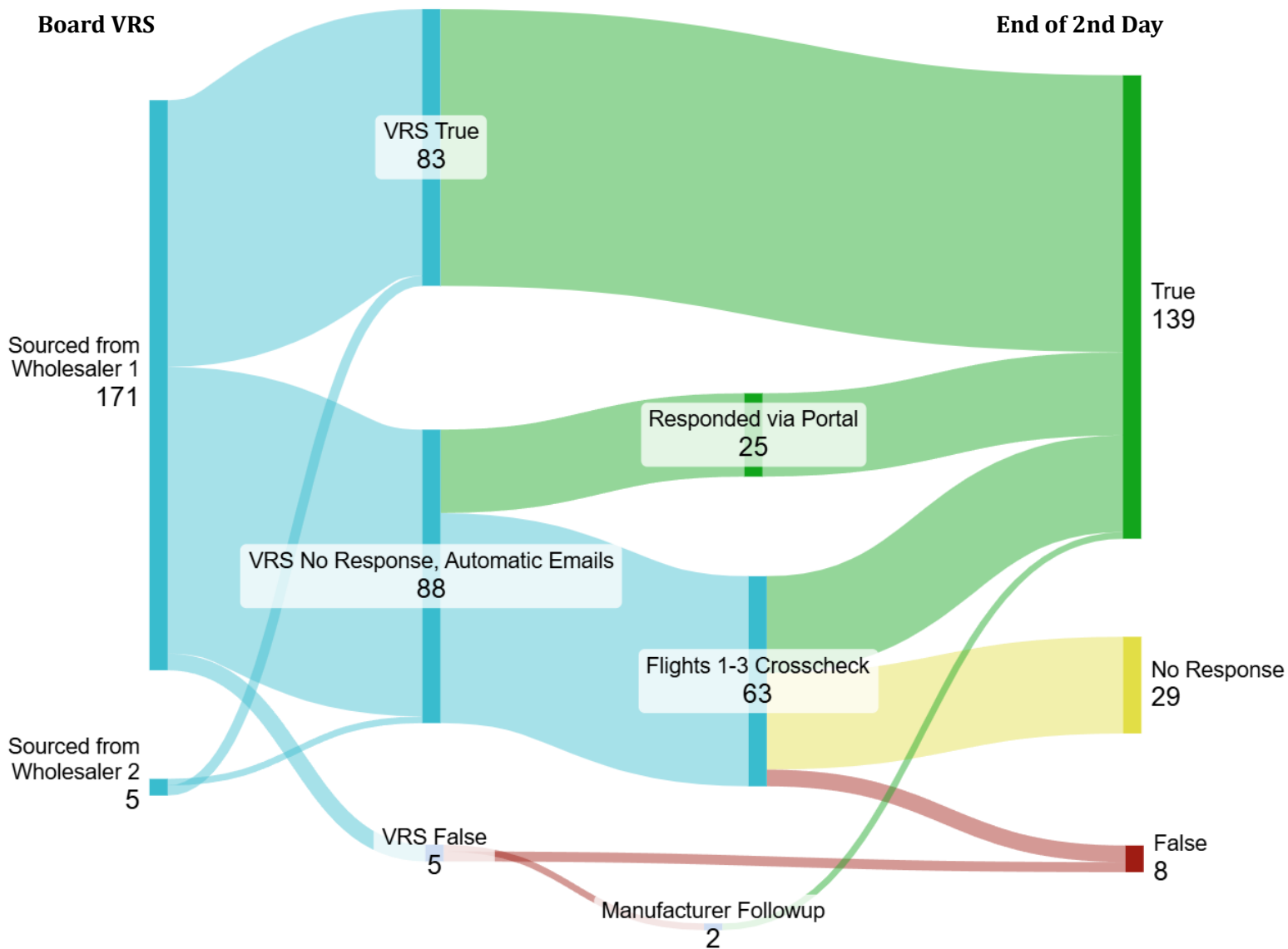
Final Results

	Flight 1: Wholesaler Uncredentialed, Previously Shared GLN	Flight 2: Wholesaler Credentialed, Previously Shared GLN	Flight 3: Board Credentialed, Previously Shared GLN	Flight 4: Board Uncredentialed, Not Previously Shared GLN
VRS True	130 (76%)	120 (70%)	123 (72%)	83 (47%)
VRS False	10 (6%)	10 (6%)	10 (6%)	5 (3%)
No Response	31 (18%)	41 (24%)	38 (22%)	88 (50%)
Total	171	171	171	176

In Flight 4, the Board sent 176 requests. 88 received VRS responses and 88 no responses.

For the 88 packages that did not receive a VRS response from that flight, emails were automatically sent to manufacturers. Over the following 24 hours, the Board received 25 responses from manufacturers, who verified packages where the VRS had not provided a response. Separately, the Board received a followup communication regarding 2 packages where VRS “false” responses had been sent in error. This left 63 requests unresolved or 36% that required followup.

In order to ascertain a more precise number of unresolved VRS requests, package status information was cross-checked against information provided in Flights 1, 2, and 3. Subsequent analysis revealed that among those 63 packages, 32 packages had received valid VRS responses in Flight 3, and 2 packages had received valid VRS responses in Flights 1 and 2. This left 29 packages that had an unknown verification status.



At the end of this entire exercise, out of 176 requests sent by the Board, verification status was obtained for 84%.

Conclusion

The Louisiana Board of Drug and Device Distributors always endeavors to enhance the security of the pharmaceutical supply chain and has taken the position that the DSCSA law affords the Board new tools to raise its game and that of its licensees. Through the use of the EDDS system, collaboration with industry stakeholders, and initiatives like VR-Day, the Board can make good on this potential and share learnings to the betterment of all. This empowers manufacturers and repackagers to ensure the integrity of their brands, wholesalers to ensure that product moves safely and effectively, and ultimately pharmacists and patients to better trust in the integrity of the supply chain.

Key findings from these efforts underscore both progress and challenges in achieving DSCSA interoperability. The VR-Day Interoperability Exercise provided actionable insights into the current state of readiness among trading partners. With an impressive 82% of product identifier verification requests ultimately yielding valid and nearly instantaneous responses via the VRS network, it is clear that the foundations for fully interoperable PI verification are fully in place.

The remaining 18% requiring manual email follow-up emphasizes the importance of continued engagement with trading partners. In the event that manufacturers do not use VRS, have set block policies, or are experiencing technical issues, The Board has an email fallback system which auto-generates a credentialed email with a human-readable request for product verification and a link to the Board's portal. (All-electronic methods are dramatically faster and easier to log than Board inspectors needing to call an 800 number!)

We also learned that procuring a GLN is not enough – we need to exchange full contact information with trading partners. While regulators are not included in the ATP confirmation requirements, we for one will hold ourselves to that standard with an annual confirmation to all ATPs and fellow regulators.

Building on these results, the Board is better equipped to refine its policies and inspection procedures, enhance collaboration with stakeholders, and make use of the interoperable EDDS. As we shared at the VR-Day meeting, Board staff has drafted a new inspection checklist that includes a section specific to each trading partner within the DSCSA community. We hope that these efforts demonstrate that together we can protect and trust the safety and integrity of prescription medications.

Finally, we would like to thank our participating Board Members – Chairman Mike Davis, Scott Irelan of Morris & Dickson, and Chad Gielen of our host Louisiana Wholesale – as well as speaker Jaidalyn Rand of HDA and in-person observers Tim Stearns (HDA) and Greg Jones and Mark Karhoff (both NABP). We are grateful for the participation of licensees for our courtesy calls including Keith LaNasa and Rebecca Risher of Sola, Lindsey Venable of Medecor, Rustin Holbert of Morris & Dickson, and Buddy Ryder of Louisiana Wholesale.

Finally, while the Board does not endorse any solution providers, we extend our thanks to the verification (Movilitas, SAP, TraceLink, LSPedia, rfxcel, Systech, and Optel) and credentialing (LedgerDomain and Spherity) solution providers who participated in the planning, execution, and audit of the four flights.