

# DSCSA 2023 Introduces New Product Verification Requirements for Pharmaceutical Manufacturers

By Dan Walles
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When the final phase of the U.S. Drug Supply Chain Security Act (DSCSA) goes into effect on November 27, 2023, it will mandate significantly expanded product verification requirements for pharmaceutical manufacturers. These additional product verification requirements fall into two categories:

Manufacturers will be required to respond to saleable returns product verification requests from anywhere in the supply chain, even if the manufacturer itself has a policy against accepting returns.

**1. Saleable Returns:** Manufacturers will be required to respond to saleable returns product verification requests from anywhere in the supply chain, even if the manufacturer itself has a policy against accepting returns. For example, when a dispenser returns products to a wholesale distributor, that distributor must verify the product with the manufacturer before it can be resold.

**2. Suspect Product Investigations:** Manufacturers will also be required to respond to verification requests that stem from illegitimate and suspect product investigations—and these requests can come from anywhere in the

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pharmaceutical supply chain, including both direct and indirect trading partners. In other words, manufacturers will see a significant increase in product verification requests from wholesalers, repackagers, and pharmacies, even if the manufacturer does not do business directly with those entities. Manufacturers must also respond to product verification inquiries from the FDA and other regulatory bodies.

If a manufacturer, or marketing authorization holder (MAH), fails to respond to a product verification request for saleable returns or suspect and illegitimate product investigations, they will be out of compliance with DSCSA. Failing to rapidly respond to verification requests could disrupt or delay its trading partners' ability to remain in compliance, resulting in damaged business relationships. It can also lead to shortages of critical medicines. Additionally, failure to comply with DSCSA verification requirements can lead to FDA fines and license suspensions. Finally, major wholesale distributors expect their suppliers to be in full compliance with DSCSA ahead of the deadline.

"Manufacturers and repackagers are already required, as of November 27, 2017, to respond to any verification request initiated by any authorized trading partner in possession or control of the product to be verified," according to guidance from the Partnership for DSCSA Governance. "The DSCSA 2023 requirements build on that foundation by requiring secure, electronic, interoperable systems and processes to carry out that verification."

DSCSA 2023 stipulates that verification responses must be received within 24 hours. However, the powerful wholesale distributor community has made it clear that it expects manufacturers to respond to verification requests in less than one second.

To ensure compliance before this year's deadline and avoid damaging critical business relationships with wholesale distributors, manufacturers should act with urgency and prepare for these new product verification requirements now. The most effective way to do that is by engaging with TraceLink, the industry's leading

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provider of trusted, cloud network-based product verification solutions.

## DCSCA 2023 product verification requirements

Product verification is the process of confirming that the four product identifiers associated with a package, including the global trade item number (GTIN), serial number (SN), lot number, and expiration date, match the information that the MAH specified when the product was initially placed into commerce. To meet this requirement, the MAH must have several capabilities in place. These include the capability to:

- Receive and respond to the verification requests from both wholesalers and dispensers.
- Verify the credentials of the requestor.
- Respond to requests in less than one second.
- Ensure interoperability using the industry-standard verification router service (VRS) model.
- Comply with GS1 Lightweight Messaging Standard governing the verification request and response process.

## GTIN and master data sharing for DSCSA 2023

With item level traceability requirements for DSCA 2023, all companies handling serialized products will need access to manufacturer GTINs and pack-level master data. Today, wholesalers and dispensers are requesting this information via email and spreadsheets. These manual, one-off processes are slow, inefficient, and often wrought with data errors. If the MAHs do not have this information, processes such as receiving and shipping may be delayed, while incorrect pack-level data can cause inventory errors. Therefore, the MAH requires a 100% electronic, interoperable, and automated way to provide GTIN and pack-level master data to direct and indirect supply chain partners.

Unique to TraceLink, and included with the verification service, is the capability to

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publish new and updated GTIN and pack-level master data that identify the MAH's product. Wholesalers and dispensers will require this information so that their systems can determine quantities and whether they are scanning items or cases. This information is currently exchanged slowly via email and spreadsheets. The TraceLink solution eliminates this problem, thereby preventing supply chain disruptions that cause detrimental effects to service, cost, cash, and sales.

### What should existing TraceLink customers do?

If you are an existing TraceLink serialization customer, we can rapidly get you up and running with Product Information Manager - Verification in just days. All it takes is five easy steps. These include:

1. Enable the VRS capability.
2. Add authorized trade partner credentials.
3. Configure your verification settings.
4. Ensure data is populated to the verification router service.
5. Validate the system.

With TraceLink, customers quickly and easily meet the verification requirement and are free to focus on other critical aspects of DSCSA compliance.

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### Why TraceLink?

TraceLink Product Information Manager - Product Verification, a solution already deployed on the TraceLink network, provides an automated verification service compliant with the VRS industry model. The solution integrates natively to the TraceLink Level 4 system as well as other provider's Level 4 systems. The solution also supports the GS1 standard for verification and the verification of requestor

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credentials. Here are some key Product Information Manager and TraceLink network metrics to consider:

- More than 60% of all GTINs synced to the interoperable VRS Lookup Directory belong to TraceLink customers and are hosted on the TraceLink network.
- More than 51,000 TraceLink customer GTINs are production-ready for DSCSA verifications.
- More than 280 customers are currently using TraceLink Product Information Manager - Verification.

TraceLink Product Information Manager - Verification delivers value and tangible business benefits for customers across four key pillars. These include:

**Network:** The TraceLink "Integrate Once, Interoperate with Everyone™" network model greatly reduces the time, cost, and risk associated with responding to product verification requests for salable returns and suspect product investigations. With TraceLink, manufacturers, dispensers, and wholesale distributors do not have to go outside of the network to process product verifications. This eliminates the delays and other risks associated with routing the request through outside systems.

**Scalability:** Between saleable returns and suspect product verifications, the number of daily requests across the industry could grow to tens of thousands per day. The TraceLink native cloud architecture has been designed, developed, and proven to manage the data and transaction processing scale required for DSCSA item-level traceability and verification. TraceLink routinely processes verification requests in less than one second. Customers of all sizes can rest assured that the TraceLink network can scale to meet all of their product verification requirements.

**Continuous Compliance:** DSCSA requirements will continue to evolve up to and after the deadline. TraceLink upgrades all network entities at once, ensuring that manufacturers have the required compliance functionality and that verification

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systems remain accessible by their customers. For example, two new versions of the GS1 Lightweight Messaging Standard have already been released, with more likely to come. TraceLink will always manage these upgrades for our customers.

**Ensure Supply:** Verification is a mission-critical process, and without successful verifications, products cannot be legally distributed or dispensed to patients. The TraceLink active-active network architecture ensures high availability with 99.95% uptime - higher than industry-standard best practices.

Time is running out for manufacturers to ensure that subsecond product verification systems are up and running. TraceLink offers a proven solution that offers the fastest, most cost-effective time to implementation and deployment. If you haven't done so already, be sure to contact TraceLink and get started now.

**Contact TraceLink to learn more about the Product Information Manager - Product Verification.**

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Contact us to learn more!
Contact TraceLink to learn more about the Product Information Manager - Product Verification.

**Thank you for contacting us; we'll be in touch shortly.**

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