RESOURCES

DSCSA Compliance: Why Specialty Pharmaceutical Manufacturers Need a Product Verification Solution

Specialty pharmaceutical manufacturers, which typically produce low-volume, high-value drugs, such as medicines for rare diseases and cell and gene therapies, are facing expanded product verification requirements under the final phase of the U.S. Drug Supply Chain Security Act (DSCSA).

In this article, we'll explain why specialty drug manufacturers need a product verification solution even if they do not accept returns, do not expect to be part of suspect product investigations, and do not expect a high number of product verification requests.

We'll also explain why **TraceLink Product Information Manager - Product Verification**, a proven digital network-based product verification solution that provides responses to product verification requests from direct and indirect trade partners in less than one second, is the fastest, most effective, and most cost-efficient way to comply with these requirements.

DSCSA Verification Requirements for Manufacturers

To understand why specialty drug makers need to leverage a product verification solution, it's important to first understand the new DSCSA verification

requirements, which impact all drug manufacturers doing business in the United States. The new product verification mandates, which take effect in November 2023 with a 12-month stabilization period per FDA guidance, fall into two categories:

1. Saleable Returns: Manufacturers will be required to respond to saleable returns product verification requests from anywhere in the supply chain. 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 pharmaceutical supply chain, including both direct and indirect trading partners. As specialty drugs usually carry a high price, they are often targeted by counterfeiters. Manufacturers must also respond to product verification inquiries from the FDA and other regulatory agencies.

"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."

What if my company doesn't accept returns?

As a specialty drug manufacturer, you may have agreements with wholesale distributors which stipulate that your organization does not accept returns for certain products. But that agreement may not apply to the wholesale distributors' pharmacy customers.

Under DSCSA, when a wholesale distributor receives a return of your product, it

must verify the product identifier before it is put back into inventory. Additionally, the wholesale distributor community has made it clear that it expects manufacturers to respond to product verification requests in less than one second. The only way to accomplish this is to use the industry-wide verification router service (VRS) through a product verification solution such as TraceLink.

Another example is cold chain drug products. Some specialty manufacturers may believe that they don't need to be concerned about saleable returns because their products are temperature sensitive and cannot be returned. What they may not realize is that pharmacies return cold chain products to wholesale distributors on a regular basis. According to the Healthcare Distribution Alliance, 100% of wholesale distributors resell temperature-controlled products that have been returned from pharmacies. When those products are returned, the wholesale distributor must verify the product identifier or they will be out of compliance with DSCSA.

What if I don't expect to be part of many suspect product investigations?

Specialty drug manufacturers often produce products in low volumes and therefore may not expect to receive many product verification requests related to suspect or illegitimate product investigations. But these types of product verification requests are unpredictable and they can come from anywhere in the supply chain, including direct and indirect trading partners, as well as regulatory authorities like the U.S. Food and Drug Administration. Most importantly, most low volume specialty drugs carry very high prices and are more likely to be counterfeited or altered.

It is impossible to know who is going to ask for these types of verification requests and when they are going to ask for them. That is why it's important for specialty manufacturers to be prepared, according to Dan Walles, General Manager of Track & Trace Compliance at TraceLink and a DSCSA compliance expert.

"If a specialty drug manufacturer gets a verification request from a dispenser or a regulatory authority as part of an investigation, they are obligated to respond to

that request," Walles said. "If they are not prepared to perform that verification, they are going to be out of compliance with DSCSA."

Can I process verification requests manually via phone and email?

Some specialty drug manufacturers may believe that there is no need to invest in a product verification solution because they produce products in low volumes and do not expect to get a high number of product verification requests. Instead, they may think that responding to product verification requests manually via phone, fax, or email is a feasible approach. The problem with this approach is that the wholesale distributor community has made it clear that they will not accept manual product verification processes.

"The wholesale distributors—particularly the big three—are dealing with millions of products that have been returned to them that they want to resell, and to make a phone call or write an email for each one is just not sustainable," Walles said. "I think the specialty manufacturers are very well-intentioned in saying that the wholesale distributors can simply call them and they will verify the product, but that is not how the wholesale distributors want to operate. One wholesale distributor indicated that it would have to build multiple warehouses to hold inventory if it were to allow for manual verification. It's just not a viable solution."

Why TraceLink?

TraceLink Product Information Manager - Product Verification provides manufacturers with the capability to receive and respond to verification requests, verify requestor credentials, and synchronize their GTINs with other lookup directories. The solution automatically creates a verification request with the wholesale distributor’s or dispenser’s credentials and routes it to the correct manufacturer. Despite the complexity of the pharmaceutical supply chain, Product Information Manager - Product Verification executes verification requests with sub-second response times, ensuring that operational processes are not delayed.

Product Information Manager - Product Verification supports the GS1 Lightweight Messaging Standard for Verification of Product Identifiers, ensuring 100% interoperability across the supply chain. This enables pharma supply chain organizations that are purchasing, distributing, or dispensing products to easily verify product identifiers for salable returns, suspect and illegitimate product investigations, and regulatory authority requests.

TraceLink Product Information Manager - Product Verification is built and hosted on the TraceLink network, the world's largest digital supply chain network, which enables manufacturers to seamlessly exchange serialized data and traceability information with direct and indirect trade partners across the supply chain. Key network metrics include:

- **60%+** of all GTINs synced to the VRS Lookup Directory (51000+ GTINs) belong to TraceLink customers and are hosted on the TraceLink network.
- **51K+** TraceLink customer GTINs are production-ready for DSCSA verifications.
- **41.1B+** product identifiers (GTIN, serial number, lot number, and expiration date) have been commissioned to date.
- **280+** customers use TraceLink Product Information Manager - Product Verification.
- **290K+** pharmaceutical supply chain stakeholders are already authenticated and onboarded TraceLink network members.

For specialty drug manufacturers, Product Information Manager is the key to ensuring compliance with DSCSA product verification mandates.

Contact us to schedule a quick meeting and get started with Product Information Manager today!

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Contact TraceLink to get started with DSCSA compliance!

Fill out the form to contact us now.

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Learn how Product Information Manager helps you reduce the time, cost, and risk associated with verifying saleable returns, managing suspect or illegitimate product investigations, and ensuring DSCSA compliance.

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