

## SALEABLE RETURNS

# VRS Capabilities and Decision Criteria for Manufacturers

Under the Drug Supply Chain Security Act (DSCSA), as of November 2018, manufacturers are required to respond to prescription product verification requests from any authorized trading partner within one business day. One year later, wholesalers will be required to verify the unique identifier of any returned product that they intend to re-distribute.

When the DSCSA Saleable Returns Verification requirement goes into effect in November 2019, the volume of verification requests to manufacturers is expected to skyrocket—and will only get bigger as non-serialized product is eliminated from the supply chain over the next several years.

In the summer of 2018, AmerisourceBergen sent a letter to pharmaceutical manufacturers outlining what the company expected from its more than 450 suppliers to minimize the impact of the November 2019 requirement. With an estimated 13 million salable returns each year, the need to verify millions of returned products represents a potentially significant disruption to the company's operations and revenue stream.

Like the other “Big 3” distributors—McKesson and Cardinal—and hundreds of smaller wholesalers, Amerisource Bergen stressed the need to execute “automatic” verification requests in near real-time to ensure continuous warehouse operations.

As manufacturers evaluate different returns verification scenarios—from both direct and indirect partners—it's becoming clear that only a solution based on open industry standards offers the flexibility and interoperability to meet both DSCSA compliance and trade partner requirements—and keep vital medicines flowing to hospitals, pharmacies, and patients.

*“The law says manufacturers have 24 hours to respond to a verification request. That could disrupt the returns process quite a bit. We need this to be an almost instantaneous response.”*

Scott Mooney  
Vice President of Distribution Operation  
McKesson Corporation

This white paper examines the advantages of using a shared information network to transmit verification requests, share serialization and product master data, and ensure secure data access only by authorized trading partners. It also includes criteria for assessing a returns verification solution to be sure that it meets current industry needs; is flexible enough to adapt to new and evolving regulations and business requirements; and provides a foundation for an all-digital supply chain strategy.

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## Overview: DSCSA Saleable Returns Verification

Since its enactment in 2013, DSCSA continues to drive industry-wide technology and process change as manufacturers, distributors, and dispensers prepare for and meet the enforcement milestones that have been established by the FDA.

A key provision of DSCSA is the Saleable Returns Verification requirement, which also takes effect in November 2019. Having identified product returns as a potential channel for introducing illegitimate medicines into the supply chain, the FDA will require wholesalers to verify the product identifier of all returned products prior to further resale and distribution. Wholesalers will also be prohibited from reselling products they did not originally sell.

Every year, nearly 60 million saleable units are returned to wholesalers. Beginning in November 2019, manufacturers may need to respond to hundreds, or thousands, of verification requests each day from their direct trading partners. And, as serialized product flows to secondary distributors, retail pharmacies, hospitals, and healthcare systems, manufacturers must be prepared to process verification requests from these "indirect" trading partners as well.

### DSCSA Timeline

#### 2015-2017

Respond to suspect product investigation

Validate TH and TI of identified product

Verify SN once product is serialized



#### Nov. 2018

Respond to SN Verification request from direct OR indirect partners

Results within 24 hours



#### Nov. 2019

Saleable Returns Verification



#### Nov. 2023

Electronic interoperable system

Product tracing to package level



Failure to respond quickly and decisively to suspect product notifications and verification requests from its downstream partners risks action by the FDA, beginning with a public warning letter to the manufacturer.”

## A Comprehensive Approach to Product Verification and Master Data

To ensure that all wholesalers have the ability to meet the 2019 saleable returns verification deadline, the Healthcare Distribution Alliance (HDA) Saleable Returns Task Force identified two complementary solutions for saleable returns verification: Verification Router Services (VRS) and self-verification using product data sent by the manufacturer with each shipment. The Big 3 wholesalers have established both methods as basic requirements for their suppliers. In addition, they have specified that manufacturers must implement a solution to provide up-to-date product master data to facilitate product verification and streamline warehouse operations.

HDA developed the VRS model to enable efficient capture, routing of, and response to verification requests at operational speed between stakeholders in the supply chain and the verification systems and related product identifier repositories of the manufacturers.

The VRS model is based on open, interoperable data exchange standards and business process guidelines that are independent of solution technology, enabling integration and seamless data exchange across a diverse ecosystem of wholesalers, manufacturers and VRS solution providers. GS1 US Healthcare partnered with the HDA task force in 2018 to take the data exchange guidelines developed by the group and turn them into formal GS1 industry standards for publication in early 2019.

A “self-verification” solution requires that manufacturers provide product identification data using the GS1 EPCIS (Electronic Product Code Information Services) standard. Instead of sending a verification request to the manufacturer, a wholesaler would check the saleable return against their own product information database. In cases where a manufacturer is not able to send EPCIS data, however, a VRS solution need to be available for product verification.

With the advent of serialized product and the saleable returns requirement, product master data—including the GTIN (Global Trade Item Number)—is critical to wholesaler processes for receiving and managing serialized product. Currently, sharing product master data is a largely manual process using XML files and spreadsheets.

*“The most important thing . . . is that manufacturers start moving to saleable returns verification now, just like wholesalers need to be doing. As an industry, we’re not going to be ready in time unless all parties get going.”*

Scott Mooney  
Vice President of Distribution Operation  
McKesson Corporation



## TraceLink's Verification Solution Framework

TraceLink's solution for saleable returns verification extends the company's standards-based Master Data, Serialization, and Product Track solutions to include Product Information Manager and its Master Data Sharing/ VRS applications deployed on the TraceLink network platform. The combination of these solutions delivers the full range of functionality that companies will need to meet their regulatory obligations as well as its trade partner requirements.



## Decision Criteria for Saleable Returns Verification

As the industry prepares for the November 2019 DSCSA Saleable Returns Verification requirement, two schools of thought offer different perspectives on the challenge, the solution, and the business strategy.

The first reduces a verification router service (VRS) to its bare components—a request including a GTIN, serial number, expiry date and lot number, and a response—and proposes an equally basic, one-size-fits all solution using a verification API. By over-simplifying the challenge, this approach allows solution providers to offer sub-optimal technology that promises short-term relief but may carry long-term consequences.

TraceLink, on the other hand, sees the VRS model as a critical business system for companies concerned about DSCSA compliance, data security, and technology ROI. As the first opportunity for manufacturers to leverage serialization data to inform business processes and improve customer satisfaction, saleable returns verification is more than a simple data lookup—and requires a more demanding set of decision criteria.

### Network Integrity and Governance

The TraceLink network provides secure integration with verified distributors, facilitates fast onboarding of new trade partners, and enables manufacturers to respond to verification requests from indirect DSCSA-authorized trading partners—without the cost and effort of creating individual point-to-point connections or forcing customer service operations to vet inbound inquiries from indirect trade partners with whom they have never engaged while the distributor is waiting for a response.

To ensure network security and authorized access, TraceLink dedicates substantial time and resources to network governance, with more than 20 full-time professionals responsible for authenticating companies on the network using the GLN (Global Location Number) and other industry-standard business identifiers to ensure that a verification query is from an authorized trading partner.

As the world's only real-time information sharing platform for the pharmaceutical supply chain, the TraceLink network is trusted by more than 650 pharmaceutical companies, 780 CMOs, 870 wholesale distributors, and 260,000 pharmacies and healthcare systems—and connects both TraceLink customers and non-customers for true, open supply chain connectivity.

### Performance at Serialization Scale

With an estimated volume of 59 million saleable returns annually, manufacturers are expected to receive as many as 7,800 daily requests that must be queried against billions of serial numbers and terabytes of data. With inventory management and customer satisfaction at stake, your VRS solution must scale to respond to each request in less than 1 second.

Solution providers with a limited customer base have not had their serialization architectures tested at the scale that will be required for near-real time verification. With more than 500 manufacturing customers exchanging data on its network, TraceLink's highly scalable native cloud platform offers demonstrated success in managing large data sets—measured in billions of serial numbers—while maintaining the operational performance required for serial number lookups and verifications.



## Integrated Master Data Sharing

As serialized product enters the supply chain, GTIN and product master data will be essential to wholesaler processes for receiving, managing, and verifying products from multiple suppliers. Wholesalers are defining their product master data requirements for handling saleable returns and querying their suppliers on how the data will be provided in digital format to eliminate time-consuming manual processes.

Only TraceLink's verification solution combines a VRS with master data sharing capabilities to help manufacturers satisfy two critical trade partner requirements with a single solution and eliminate the need to contract with a separate provider for sharing GTINs and product master data with downstream customers. If you are already a TraceLink customer, making master data available to trading partners as part of your complete verification solution requires no additional effort.

For companies that maintain their product data repositories with TraceLink, master data sharing and verification capabilities are pre-integrated into their end-to-end solution, so any changes to product master data will automatically be available to trade partners. In addition, new GTINs are automatically registered with the TraceLink VRS which, in turn, synchronizes across the other approved industry lookup directories.

## Data Access and Partner Authentication

DSCSA requires that manufacturers respond to verification requests from any authorized trading partner, whether direct or indirect, which may be a 2nd- or 3rd-level distributor, pharmacy, or even a prescribing doctor's office. But how can you be sure the request for sensitive information is coming from a legitimate, authorized business entity?



Serialization data and product master data used for product verification must be treated as sensitive, proprietary information. The TraceLink network provides a proven, trusted channel that authenticates verification requests against a database of more than 512,000 business identifiers—including the GS1 Global Location Number (GLN), Dun & Bradstreet Data Universal Numbering System (D&B DUNS) number, U.S. Drug Enforcement Agency (DEA) registration number, and the Health Industry Business Communications Council Healthcare Identification Number (HIN).

## Standards and Interoperability for Easier Integration

TraceLink leverages the interoperability standards defined in partnership with the HDA verification task force and GS1 US Healthcare, ensuring that your TraceLink verification solution will be able to receive—and respond to—your customers' verification requests regardless of the solution they choose. More than 195 TraceLink customers from 93 companies—from pharma manufacturers to healthcare organizations—have participated in TraceLink's solution innovation group to ensure that critical business challenges associated with saleable returns verification and master data sharing are being addressed by TraceLink's product development teams.

TraceLink's information-sharing platform, Product Information Manager, seamlessly integrates with TraceLink's existing master data and serialization solutions—or can integrate with third party master data, Level 4 serialization repositories or other business systems such as WMS or ERPs.

As TraceLink serialization customers commission new serial numbers, the GTIN, serial number, lot number and expiration date are automatically published to Product Information Manager so that they are available for verification—as a saleable return or as a suspect product.



## Next Steps: Digital Transformation

For pharmaceutical manufacturers, saleable returns represent much more than a technology challenge for responding to verification requests. At stake are overall customer satisfaction and healthy partner relationships; fewer chargebacks and improved product availability; reduced administrative overhead; and a new source of insight into product movement and consumption.

The key to leveraging saleable returns for business advantage relies on real-time information sharing and a highly scalable, high-performance platform that supports your company's long-term digital transformation. Only the TraceLink network provides the connectivity and capacity you need to implement a complete verification strategy today—and position your company to realize the potential of the digital supply chain of the future.