

Under the U.S. Drug Supply Chain Security Act (DSCSA), manufacturers, wholesale distributors, health systems, and retail pharmacies face a range of product identifier verification requirements. Product identifiers, which include the GTIN, serial number, lot number, and expiration date, must be verified as part of saleable returns processes, suspect or illegitimate product investigations, and when responding to requests from the U.S. Food and Drug Administration or other regulatory bodies.

# **Product Information Manager - Product Verification**

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.

# **Key Capabilities**

- **Serialized Data Verification:** Verify serialized product identification data, including GTIN, lot number, expiration date, and serial number.
- Verification Response Management:

  Manage responses to verification requests
  with the capability to return "positive" or
  "negative" verification results as well as
  additional product status information, such
  as "recalled," "expired," and more, in less
  than one second.
- VRS Support: Fully supports the industrystandard Verification Router Service (VRS) network model and related GS1 standards, including use cases for both requesters and responders.
- VRS Lookup: TraceLink has the most innetwork GTINs in the industry. More than 60%—51,000+ GTINs—of all GTINs synced to the VRS Lookup Directory belong to TraceLink customers and are hosted on the TraceLink network. With TraceLink, product GTINs are published and maintained in the VRS Lookup Directory, enabling rapid network routing of verification requests from VRS systems to the correct manufacturer or repackager responder system.
- Network Connectivity: Users gain access to a secure and comprehensive, network-based repository of serialization data and product statuses, enabling rapid verification requests and responses from both direct and indirect trading partners across the end-to-end supply chain.
- Sub-Second Responses: Designed to deliver the scalability and performance organizations need to exceed operational requirements, including the industry mandate for sub-second responses to verification requests.

# REAL-WORLD CASE STUDY

### **COMPANY PROFILE:**

Multinational pharmaceutical manufacturer with \$15B+ in annual revenue.

### **BUSINESS CHALLENGES:**

- The manufacturer needed a way to process product verification requests for saleable returns and suspect or illegitimate product investigations as required by DSCSA.
- The wholesale distributor community requires manufacturers to respond to product verification requests electronically in less than one second.
- The number of verification requests received on a daily basis is unpredictable—anywhere from 10 to 100—and are expected to rise dramatically when the final phase of DSCSA takes effect in November 2023.

#### **SOLUTION:**

 Product Information Manager - Product Verification

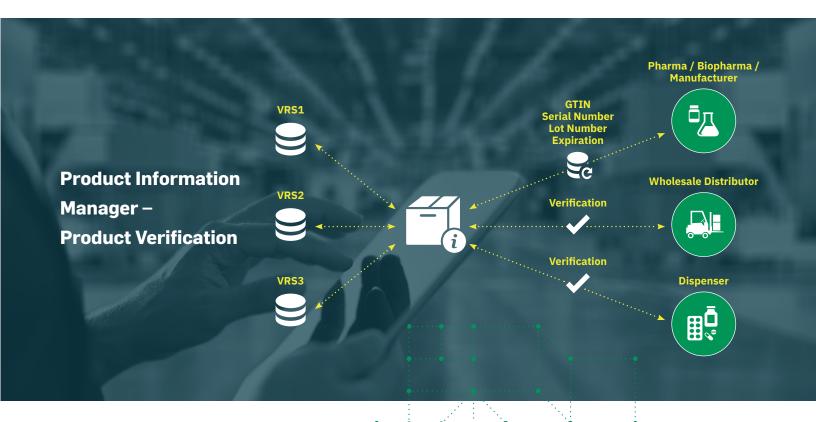
### **RESULTS:**

- The company now uses Product Information Manager - Product Verification to process verification requests from both direct and indirect trading partners with sub-second response times.
- The solution, which runs on the TraceLink network, was easy to set up, and the automatic processing of verification requests is fast and simple.
- The vast majority of the manufacturer's downstream trade partners were already on the TraceLink network. With TraceLink, the manufacturer now has the capability to process verification requests with more than 380 trade partners electronically and with 100% interoperability.

# **Key Benefits**

- Business-to-Network, Integrate-Once™: The

  TraceLink network model empowers all manufacturers,
  wholesale distributors, and dispensers to "Integrate
  Once, Interoperate with Everyone™." Because TraceLink
  is the leading verification solution with hundreds of
  pharmaceutical manufacturer customers, the majority
  of verifications happen in-network, ensuring the fastest
  response time.
- Scalability: With new product verification and item-level traceability requirements going into effect as part of the DSCSA 2023 mandate, the number of daily verification requests across the end-to-end U.S. pharma supply chain is expected to increase dramatically. The TraceLink native cloud architecture is designed, developed, and proven to manage data and transaction processing at the scale required to support DSCSA item-level verification within operationally-intense environments. As verification requests increase during peak times, the solution automatically scales to meet that demand and ensure the sub-second response time required by wholesale distributors.
- Continuous Compliance: DSCSA verification requirements will continue to evolve and change over time. TraceLink continuously monitors evolving DSCSA requirements, new standards, and trade partner requirements. New compliance requirements are rapidly applied across the network so that all trading partners are upgraded at the same time and out-of-sync transactions are eliminated. TraceLink ensures that customers are in continuous compliance.
- Ensure Supply: Under DSCSA, products must be verified as part of the saleable returns process and suspect or illegitimate product investigations or they cannot be resold or dispensed. The TraceLink network architecture delivers greater than 99.95% uptime—higher than industry-standard best practices—helping organizations ensure that products are rapidly verified and delivered to patients on time, in full.



# Already a TraceLink Customer? Get Started Now!

For existing TraceLink customers with a license for Product Information Manager - Product Verification, getting your verification solution activated and tested is fast and easy.

JUST FOLLOW THESE FIVE SIMPLE STEPS:



Enable the VRS capability.



Add authorized trade partner credentials.



Configure verification settings.



Ensure GTINs are published to the Lookup Directory.



Validate the system.

Remember: If you need assistance, the TraceLink Solutions Consulting Team is available to help. If you are an existing TraceLink Product Track or Serialization customer with DSCSA verification needs, TraceLink can help you as well. Contact your TraceLink account representative to get started with Product Information Manager - Product Verification today.

## **About TraceLink**

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

### 60%+

of all GTINs synced to the VRS Lookup Directory (51000+ GTINs) belong to TraceLink customers and are hosted on the TraceLink network

### 290K+

pharmaceutical supply chain stakeholders are authenticated and onboarded TraceLink network members

# 51K+

TraceLink customer GTINs are production-ready for DSCSA verifications

## 280+

customers use TraceLink Product Information Manager

- Product Verification

### 41.1B+

product identifiers (GTIN, serial number, lot number, and expiration date) have been commissioned to date

Schedule a meeting with TraceLink to ensure compliance with the DSCSA product verification requirement.

