Be Compliant with DSCSA VRS Requirements with traceREADY
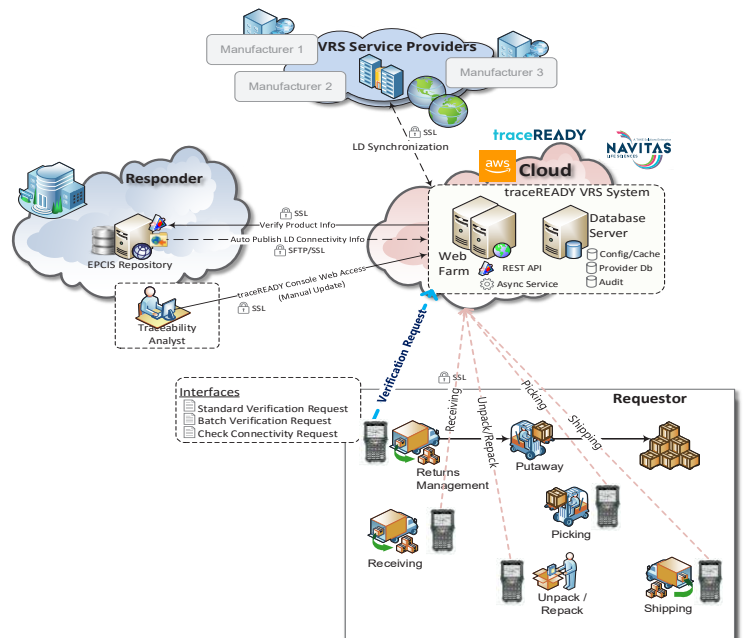

Introduction

Verification Router Service (VRS) – is a key step towards compliance with the US Drug Supply Chain Security Act (DSCSA). VRS enables pharma wholesalers in the US to validate returned pharmaceutical products before they are put back into commercial distribution. A VRS solution manages the acceptance, formatting, and delivery of requests and responses in compliance with DSCSA verification requirements.

The DSCSA requires US wholesalers to carry out such verifications in order for returned serialized products to be resold. As nearly 60 million packages of salable goods are returned to wholesalers each year, it is in the interest of pharmaceutical manufacturers to ensure that these products are not wasted. The Healthcare Distribution Alliance (HDA) brought together key stakeholders across pharmaceutical manufacturers and distributors to define best practices for VRS.
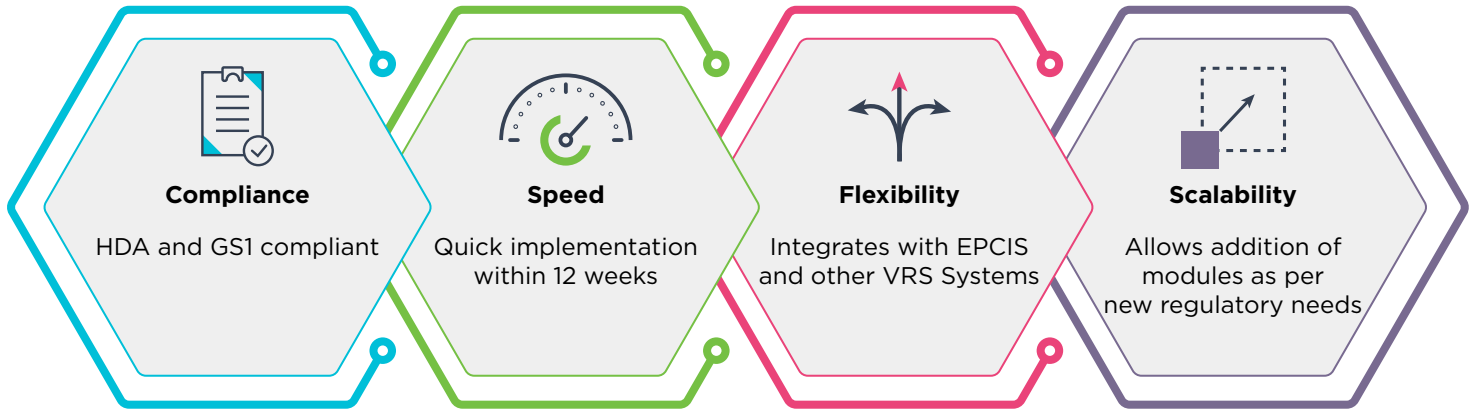
Navitas Life Sciences is a part of the HDA Work Group to develop an integrated VRS solution

traceREADY VRS Solution

Our **traceREADY** VRS Solution is in accordance with the best practices recommended by the HDA and meets the DSCSA requirements for salable returns. The **traceREADY** VRS solution integrates with your EPCIS, as well as with other VRS providers, ensuring you can easily manage your salable returns. Our in-built workflow engine is highly flexible, connects seamlessly with ERPs, scalable for large enterprise, customizable to customers' business process.

traceREADY Delivers Results

Compliance
HDA and GS1 compliant

Speed
Quick implementation within 12 weeks

Flexibility
Integrates with EPCIS and other VRS Systems

Scalability
Allows addition of modules as per new regulatory needs

Our VRS System

traceREADY's VRS Gateway caches responder/VRS connectivity information from the lookup directory for improved overall system performance

Security Provider manages authentication and authorization of VRS identities to interface with **traceREADY** Console, REST/SOAP API and Lookup Directory Synchronization Service

VRS Request Processor uses the configurable VRS Validation Engine to apply the standard rules and updates as standards mature

Persistence and transaction manager ensures data consistency and interfaces with backend databases

Audit Trail Component captures a log of all activities on the **traceREADY** VRS Gateway

Cache Provider

Security Provider

VRS Web UI

VRS Rest API

LD Sync Service

VRS Validation Engine

VRS Request Processor

Persistence/ Transaction Manager

Persistence/ transaction Manager

Key Advantages of the traceREADY VRS Solution

Multi-Tenant Cloud Hosted Solution Developed with Life Sciences Focus

Our off-the-shelf, HDA & GS1 specifications-compliant VRS solution is hosted in a multi-tenant cloud environment. **traceREADY** VRS solution reduces the risk of revenue loss due to unverifiable returns. The solution supports request and response services in a single interface and can be implemented quickly at your location.

Easy to Configure VRS Solution with Flexibility to Meet Future Regulatory Changes

Our easy, on the go configuration enables future initiatives using the VRS with no impact on the current architecture. The application is capable of capturing information from standardized barcode format with **traceREADY** VRS Configurator allows process owners to easily reconfigure Business rules and Work-flows such-as: Configuration of Email notifications, Ability to populate master data / Lookup directory, User authentication from multiple sources, etc. Our easy, On-the-go configuration enables the required barcode format with an inbuilt parser supporting multiple barcode standards like GS1, PPN.

Rich UI and Navigation with Multi-Device Support

traceREADY VRS has a native application (Windows, Android, iOS, Windows 10) that ensures a rich user experience. Our VRS system is device agnostic (right from Industrial handheld, Smart phones, Tablets, to Laptops and Desktop computers). **traceREADY** VRS's intuitive navigation is based on configured Business Processes and reduces training time as one configuration and business rules are rendered in multiple form factors. **traceREADY** VRS's multi-scan feature enables high volume transaction processing to ensure your system runs smoothly.

Scalable Architecture to Accommodate Growth

traceREADY employs a multi-threading architecture to handle volumes of inputs and enhance the user experience. **traceREADY** VRS offers compelling features to handle asynchronous transaction exceptions.

21 CFR Part 11 and Annex 11 Compliant

traceREADY is 21 CFR part 11 and Annex-11 compliant application. It has well defined Project Execution Process and Governance Model meeting ISO 9001 Standards. **traceREADY** integration is certified by SAP.

Get Your VRS system the traceREADY Edge

traceREADY has unique processes in background which can aggregate all verification requests to batch it up so that operators do not wait for every verification and with more than 100,000 units of salable returns annually this would help your EDGE system considerably. **traceREADY**'s VRS application is scalable and can be loaded in server farms. The load is monitored and the system is highly scalable by deploying additional servers to handle the extra load as they occur.

traceREADY architecture has handled large volumes of verification processes with major pharma drug logistics companies, having more than 40 sites and 300,000 shipments per day. Navitas Life Sciences has taken this Verification process and extended the same to build the VRS application.

High Performance Throughput

Proven and Stable Solution

Seamless Connectivity

Integrated Scanning Solution

traceREADY EDGE solution is integrated with VRS. This provides you an option to use the integrated system including returns system and integrated to external applications. **traceREADY** EDGE application can be extended to Hand held devices and also can be operated using web browsers. Overall, this will decrease the end-to-end implementation cost and timeline.

traceREADY is integrated with all leading Level 4 EPCIS providers, to enable easy access to your internal Level 4 systems. Navitas Life Sciences has created a service desk to maintain and verify the addresses of all responding system, thereby offering improved connectivity to your suppliers.

About Navitas Life Sciences

Navitas Life Sciences delivers platform-driven full-service Clinical, Regulatory and Safety solutions and services. As the dedicated life sciences brand of TAKE Solutions, Navitas Life Sciences operates across North America, Europe, Asia pacific and Latin America. Navitas Life Sciences combines the knowledge and experience of three legacy brands - Ecron Acunova, Navitas, DataCeutics, KAI Research and Intelent. Thus, Navitas brings together the capabilities of a full-service CRO, a technology-led life sciences services provider, and expertise in analytics and data sciences to address critical challenges and drive outcomes for life sciences. Navitas Life Sciences has over 30 years of rich experience across 400+ phase I-IV clinical trials, 20+ therapeutic areas, and 40+ successful GCP/non-GCP audits. Our trial expertise is augmented by OneClinical, a platform that delivers trial oversight, analytics, and insights to drive successful study outcomes.

For more information

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