What Is VRS and How Is It Useful for DSCSA 2023 and Beyond?[1]

Background

According to an HDA member survey, saleable returned pharmaceuticals comprise 2 to 3 percent of pharmaceutical distributors' total annual sales — representing nearly 59 million units. Given the volume of returns that distributors must process, HDA, working with Ernst & Young LLP (EY) and HDA's Traceability Pilots Work Group (Work Group) evaluated nine real-life scenarios or methods that could theoretically be employed to help meet the 2019 saleable returns requirements. Seven pharmaceutical manufacturers and six wholesale distributors from the Work Group participated in the pilots. The hope was that the results of the pilot study would allow stakeholders to reach consensus on which solution(s) would work best. The Work Group held seven workshops in which participants systematically assessed the impact of the scenarios upon manufacturers and wholesale distributors in terms of processes, cost, work and technology. The objectives of the pilots were to:

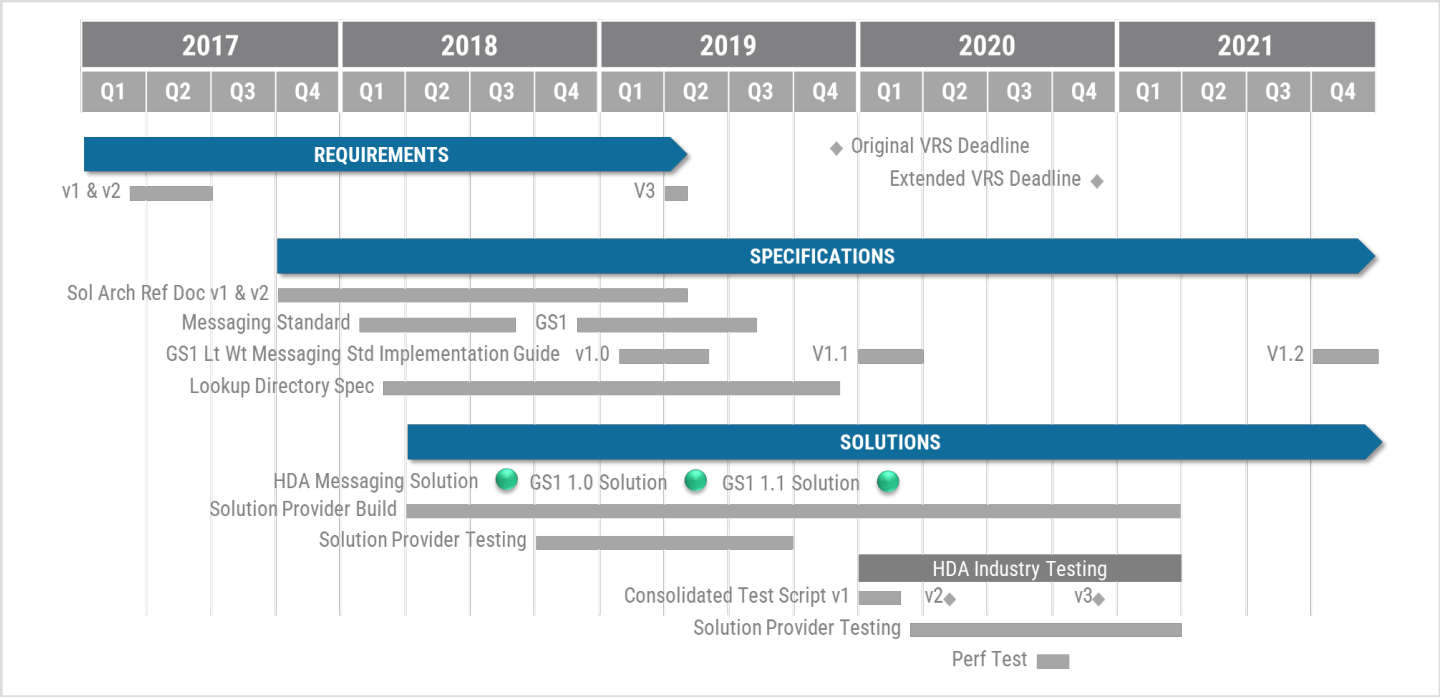
1. Provide data to the Food and Drug Administration (FDA) to illustrate the realities faced by manufacturers and wholesalers in processing and verifying saleable returns under the DSCSA.
2. Demonstrate that manufacturers and wholesalers are taking the DSCSA requirements seriously and are actively working to incorporate them into routine business processes.
3. Illustrate to FDA and other members of the supply chain the relative practicality of possible methods for returns verification.
4. Begin the process of building consensus on likely approaches that will work without adding significant burden to the supply chain.

The Work Group presented the results of its Pilot Study for Saleable Returns at HDA's Traceability Seminar in Washington, D.C. (held November 9–11, 2016), recommending two scenarios that it believes would help pharmaceutical manufacturers and wholesale distributors comply with the DSCSA requirements. The Work Group determined that these two scenarios were the most cost-effective and viable approaches to verifying saleable returns.

In the Work Group's first recommended option, a manufacturer sends to each individual wholesale distributor customer aggregated product identifier information for only the units of product that the manufacturer sold to that individual wholesale distributor; when the wholesale distributor processes a saleable return, the wholesale distributor references an internal database that it created from the information provided by the manufacturer to verify the product identifier information.

The second option the Work Group recommended employs a verification router service (VRS). In this scenario, each manufacturer stores its product identifier information in a local database, which is connected to a third-party routing service. Upon receiving a saleable return, the wholesale distributor captures the product data and sends the data to this third-party router service, which then routes the query to the appropriate manufacturer's database to verify the product's identifier.

1– This document is not intended to provide legal advice. The reader is cautioned that it cannot cover all elements of the DSCSA and we refer you to FDA, the DSCSA (and implementing guidance) and/or to their own legal counsel for more information.



Continuously Evolving: The VRS has been undergoing changes for more than five years to keep pace with industry advancements and has been in production since 2020.

Different Type of DSCSA Implementation: Unlike previous DSCSA implementations (i.e., T3s, EPCIS), VRS (and ATP) are unique because they require two-way (synchronous) communication.

Interoperability is the Key to Success: Because of the two-way nature of VRS (and ATP) all implementors of VRS (and ATP) must pass a detailed set of send/receive test cases.

Listening to the Industry (VRS 1.3): VRS is undergoing a change to meet DSCSA requirements while supporting future needs.

VRS Capabilities

- Plays a critical role in the set of tools for product investigation support
- Enables verification of product identifiers for suspect or illegitimate product investigations, exception processing, status check and saleable returns
- Additional status information can be returned on product verification:
  - Recalled
  - Expired
  - Extended Expiration
  - Suspect
  - Illegitimate
  - Verify ATP Status of Indirect Trading Partners