The Verification Router Service (VRS) Task Force Report to Industry

Facilitated by HDA

April 2019

The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors—the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA Research Foundation, HDA's non-profit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues. For more information, visit **www.hda.org**.

The Challenge

In 2013, Congress passed the Drug Supply Chain Security Act (DSCSA) which fundamentally changed how the pharmaceutical industry identifies and handles prescription drug products throughout the supply chain. One of the key provisions of this law is the November 27, 2019 requirement for wholesale distributors to verify the product identifier for each sealed homogenous case or package prior to reselling a returned product. To understand the operational impact of this requirement, the Healthcare Distribution Alliance (HDA) surveyed industry and determined 2–3% of total sales consistently come back as saleable returns. At nearly 60 million units a year, industry needed to find solutions that would efficiently and accurately verify product identifiers at scale with a sub-second time requirement to minimize the impact to existing processes and keep product moving in the supply chain. Saleable returns are critical to ensure good product makes it back into inventory and does not hinder product availability for patients. Importantly, while these occur today, DSCSA necessitates changes to existing processes and collaboration between manufacturers and distributors to be successful.

The HDA formed the Traceability Pilots Work Group in 2015 with manufacturers and distributors to focus on a pilot study of nine (9) potential methods or solutions to meet the 2019 Saleable Returns DSCSA Requirements. Through the process of evaluating nine scenarios, the Work Group acknowledged no single solution for the supply chain existed, and put forward two preferred options, keeping in mind solution cost, implementation effort, process execution, exception handling, and other advantages and disadvantages. One of the preferred options was sending aggregated data to downstream trading partners, and the other was a Verification Router Service (VRS). A proof of concept was successfully built and utilized during a live pilot, but it was only a temporary system for the purpose of the pilot. (For the full 2016 pilots report, see https://healthcaredistribution.org/resources/hda-saleable-returns-pilots-report.) At the conclusion of the pilot study, the Work Group determined that the Verification Router Service was a method worth pursuing given that many manufacturers did not intend to send data prior to 2023 and may not have planned to aggregate products by 2019.

Verification

Beginning on **November 27, 2019**, before it may resell a returned product, "the wholesale distributor shall verify the product identifier, including the [SNI] … for each sealed homogeneous case or on each package" [§ 582(c)(4)(D)].

"Verification" or **"verify"** means determining whether the product identifier affixed to, or imprinted upon on a package or homogeneous case corresponds to the [SNI] … assigned to the product by the manufacturer or the repackager…." [§ 581(28)].

A manufacturer who receives a verification request from a repackager, wholesale distributor, or dispenser must respond to that request within **24 hours** (or such other time FDA establishes) [§ 582(b)(4)(C)].

A repackager also has **24 hours** to respond [§ 582(e)(4)(C)].

Saleable returns statistics

Annual Saleable Returns – Unit Volume:

~59 Million Units

2-3% of total sales are saleable returns

Annual Saleable Returns – Return Lines:
~31 Million Lines

Peak # Saleable Returns Units/Day for DC:
4,500 Units

Peak # Saleable Returns Units/ Day for Large DC:
10,000 Units

Weekly/Daily Breakdown

~1.1 Million Units/Week

~226K Units/Day

Large Distributor Annual Volume: **~19 million**

Avg. Distributor Annual Volume: **~475 thousand**

Large Generic Manuf. Annual Volume: **~2 million**

Large Branded Manuf.Annual Volume: **~1.8 million**

Average Manuf. Annual Volume: **~90 thousand**
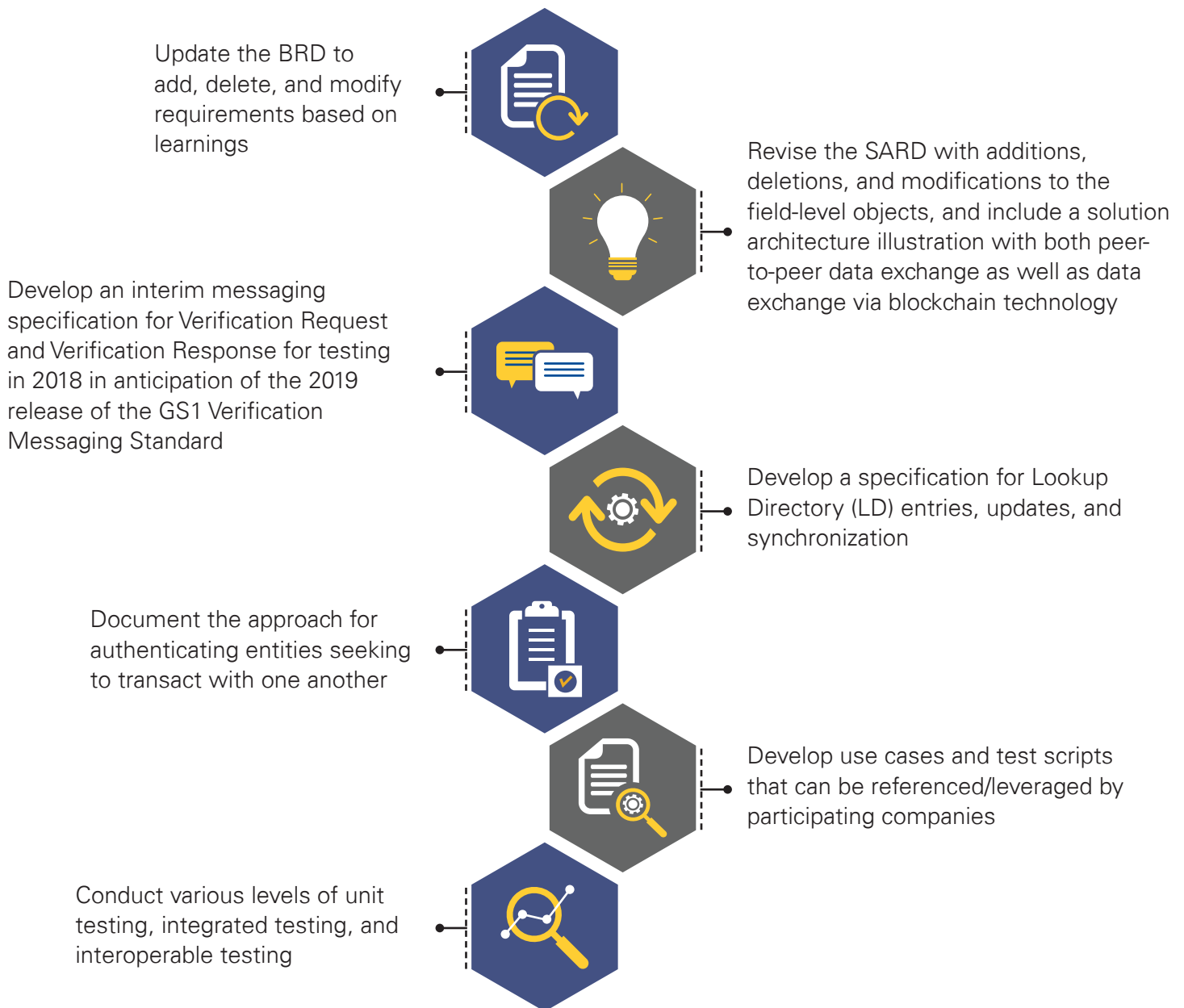
HDA Distributors surveyed**

Companies:
34

Facilities:
203

**Source: HDA 2016 Fact book

*Data is based on survey conducted with HDA members and returns processed by participating wholesale distributors from November 2014 – October 2015
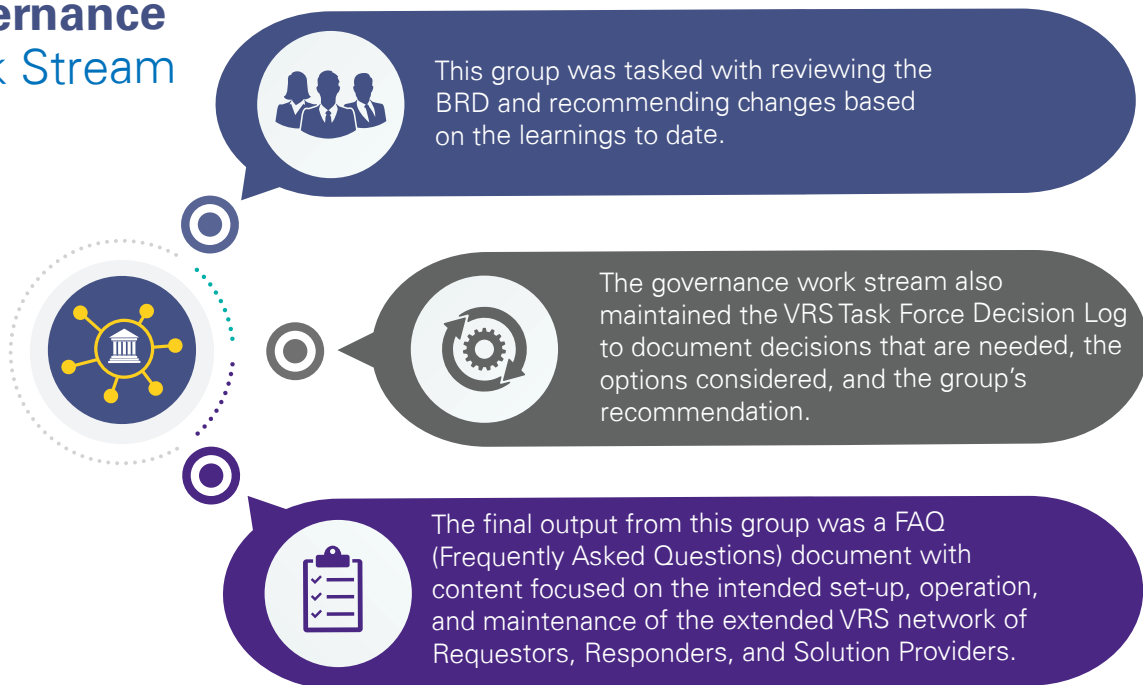
A Collaborative Effort …

HDA subsequently formed the VRS Task Force in 2017 consisting of industry stakeholders and later expanded to include solution providers. Throughout 2018, the Task Force has continued to be a collaborative, coordinated effort amongst manufacturers, distributors, and solution providers. The Task Force, working with KPMG LLP developed the Business Requirements Document (BRD) for the Verification Router Service which was approved by the VRS Task Force and published in July 2017. Subsequently, the group developed the Solution Architecture Reference Document (SARD) in 2017 in order to document the solution architecture components, their interactions, and various design and operational considerations. In 2018 the following goals were identified by the group:
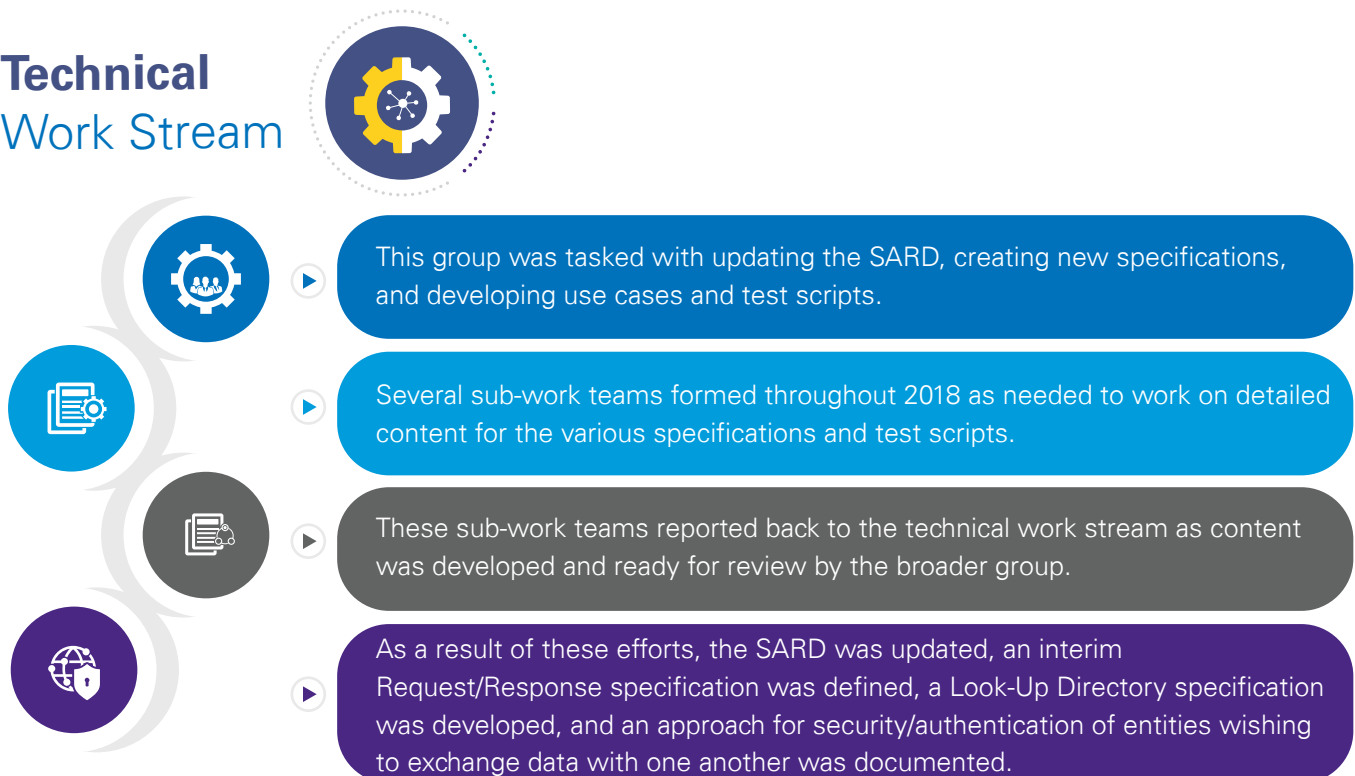
Update the BRD to add, delete, and modify requirements based on learnings

Revise the SARD with additions, deletions, and modifications to the field-level objects, and include a solution architecture illustration with both peer-to-peer data exchange as well as data exchange via blockchain technology

Develop an interim messaging specification for Verification Request and Verification Response for testing in 2018 in anticipation of the 2019 release of the GS1 Verification Messaging Standard

Develop a specification for Lookup Directory (LD) entries, updates, and synchronization

Document the approach for authenticating entities seeking to transact with one another

Develop use cases and test scripts that can be referenced/leveraged by participating companies

Conduct various levels of unit testing, integrated testing, and interoperable testing

VRS Task Force Work Streams

In order to achieve the 2018 objectives, the task force utilized two main workstreams:

Governance
Work Stream

This group was tasked with reviewing the BRD and recommending changes based on the learnings to date.

The governance work stream also maintained the VRS Task Force Decision Log to document decisions that are needed, the options considered, and the group's recommendation.

The final output from this group was a FAQ (Frequently Asked Questions) document with content focused on the intended set-up, operation, and maintenance of the extended VRS network of Requestors, Responders, and Solution Providers.

Technical
Work Stream

This group was tasked with updating the SARD, creating new specifications, and developing use cases and test scripts.

Several sub-work teams formed throughout 2018 as needed to work on detailed content for the various specifications and test scripts.

These sub-work teams reported back to the technical work stream as content was developed and ready for review by the broader group.

As a result of these efforts, the SARD was updated, an interim Request/Response specification was defined, a Look-Up Directory specification was developed, and an approach for security/authentication of entities wishing to exchange data with one another was documented.
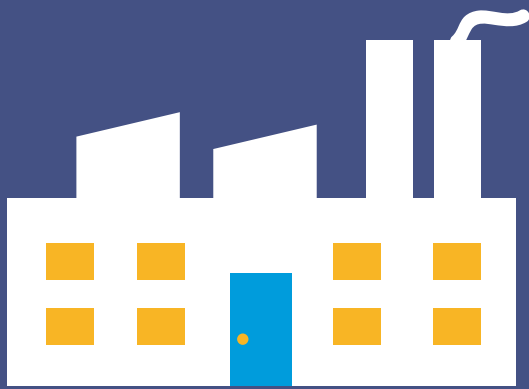
The work streams and sub-work teams met over fifty times during the course of 2018. The output of the task force includes the aforementioned documents as well as various project artifacts. The project artifacts include the following documents

Business Requirements Document (BRD)

Data Dictionary

Solution Architecture Reference Document (SARD)

Connectivity Status Matrix

Lookup Directory (LD) specification

GS1 Lightweight Messaging Standard for Verification of Product Identifiers: https://www.gs1.org/verification-messaging

Decision Log

Governance Charter

Participant Registry – **five** distributors, **eleven** manufacturers, and **eight** solution providers

Current security approach

Expectations of participating Solution Providers

Frequently Asked Questions Document

Interaction Diagram

All documents are located on the HDA Web site at:
https://www.hda.org/issues/pharmaceutical-traceability

Testing Scope

During the second half of 2018, priority test scripts were executed to test participating wholesale distributor's (requestor) creation of messages, routing of messages to a manufacturer's (responder) PI repository, formulation of responses, and delivery or responses back to the wholesale distributor (requestors).
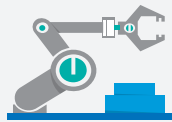
Testing occurred **across eight manufacturers**

Four distributors
were able to successfully create verification requests using both a portal-based method as well as through using the solution provider's Application Program Interface (API) to initiate the verification request

A total of
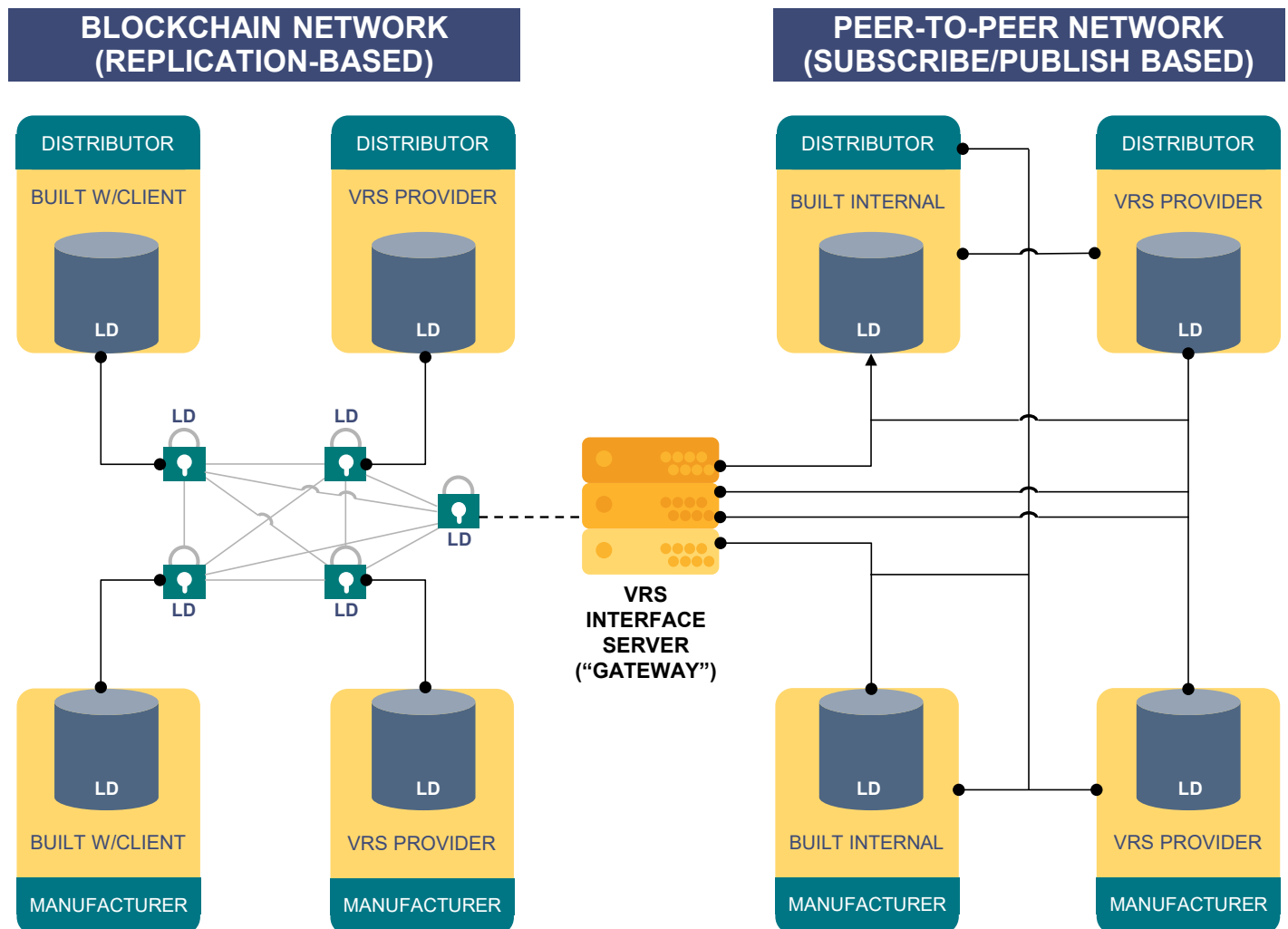**74 GTINs**
were made available for testing

Test systems from **six solution providers**

The VRS Network

From the beginning, as outlined in the SARD, the assumption has been that the network would consist of multiple VRS providers operating in a distributed environment. Over the course of 2018 two technological approaches to the VRS emerged. Illustrated in 3.3.1 is a depiction of the network. This architectural design utilizes a defined "gateway" as the conduit for directing Request, Response, and Lookup Directory data that has enabled a VRS ecosystem comprised of both participants using blockchain, replication-based technology, as well as those using peer-to-peer, publish/subscribe technology.
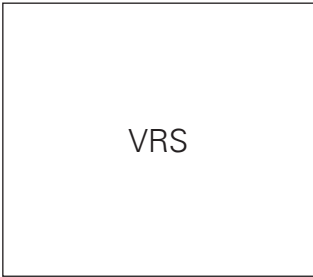
Illustration 3.3.1: VRs are routed within a blockchain and between blockchain/non-blockchain systems

BLOCKCHAIN NETWORK
(REPLICATION-BASED)

DISTRIBUTOR — BUILT W/CLIENT — LD
DISTRIBUTOR — VRS PROVIDER — LD
LD · LD · LD · LD · LD

BUILT W/CLIENT — LD — MANUFACTURER
VRS PROVIDER — LD — MANUFACTURER

VRS INTERFACE SERVER ("GATEWAY")

PEER-TO-PEER NETWORK
(SUBSCRIBE/PUBLISH BASED)

DISTRIBUTOR — BUILT INTERNAL — LD
DISTRIBUTOR — VRS PROVIDER — LD

BUILT INTERNAL — LD — MANUFACTURER
VRS PROVIDER — LD — MANUFACTURER
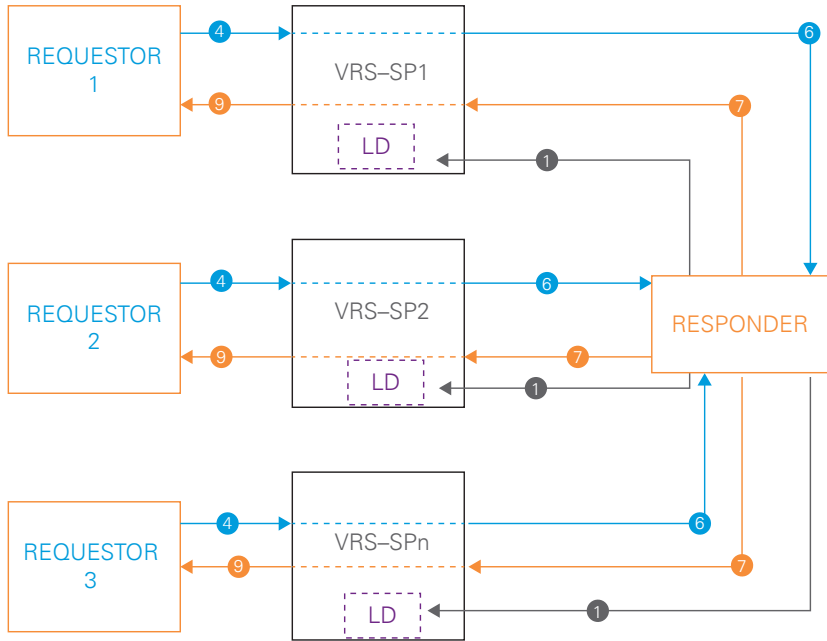
Understanding the VRS components

It is important to understand where a company fits in the network and what is required of each role. "Requestors" are wholesale distributors or an entity that initiates a verification request. "Responders" are manufacturers or an entity that replies to a verification request confirming whether or not the four product identifier elements are verified using the GS1 Lightweight Messaging Standard for Verification of Product Identifiers. The VRS and LD components are either operated by a solution provider or a company can choose to build their own requesting or responding services. Additional details are available in the SARD, LD Specification, and other documentation.

VRS Components

REQUESTOR	The Requestor's System is used for the following processes: 1) Create verification request 2) Submit verification request 3) Receive verification response
RESPONDER	The Responder's System is used for the following processes: 1) Provide Connectivity Information (CI) to VRS Provider(s) 2) Receive verification request 3) Formulate response 4) Provide verification response to requesting system
VRS	The Verification Router Service solution to be provided by multiple vendors, represented as P1, 2, …n. The VRS is used for the following processes: 1) Receive request 2) Route request to responder or responder's VRS 3) Obtain response from responder or responder's VRS 4) Provide response to requestor
LD	The Look-Up Directory which is envisioned to be an integrated component of the VRS. The LD is used for the following processes: 1) Add new GTIN records 2) Maintain GTIN records 3) Exchange GTIN records with other VRS Providers

Solution Architecture

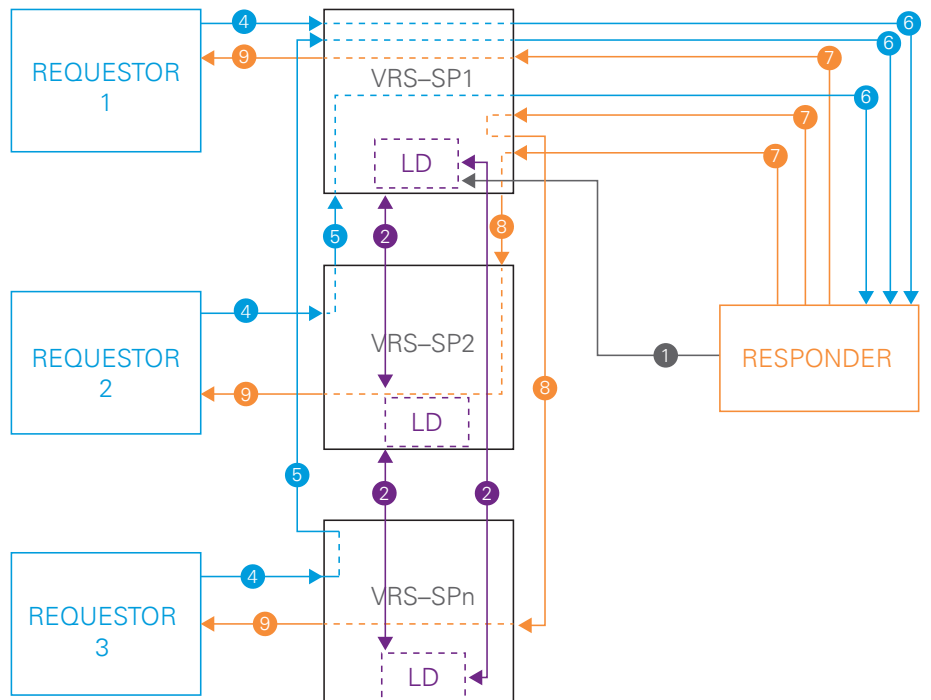**Illustration 3.3.2: VRs routed through the VRS Provider of the Requestor**

In this scenario the Responder provides their Connectivity Information (CI) directly to each VRS solution provider as part of the Responder's on-boarding/security access procedure. Interaction #2 is therefore not in scope for this scenario. This scenario has also been referred to as the "Responder Build It Yourself" model as the Responder will manage their own solution for issuing responses to verification requests from entities for which the Responder also manages access.

■ Request ■ Response ■ Responder GTIN Repository Info

Illustration 3.3.3: VRs routed through the Responder's VRS Provider

In this scenario the Responder's VRS solution provider Connectivity Information is shared across VRS providers. Interaction #1 is therefore between the Responder and their selected VRS Provider.

■ Responder VRS Provider ID at GTIN level
■ Request
■ Response
■ Responder GTIN Repository Info

Are you ready?

Below is a checklist that can be used to prepare and assess your company's readiness for the 2019 DSCSA saleable returns requirement.

1) Make your company's leadership aware of the challenge. Also, discuss the issue with your trade associations and educate yourself and your team on the impact of saleable returns to your company.

2) Ensure your master data is organized and clean.

3) Review the BRD and technical requirement documents so you have an understanding of functionality. Use these documents as reference when working with internal and external IT groups.

For manufacturers:

1) Does your company currently have a process in place for supporting verification requests from trading partners (direct and indirect)?

2) Do you have co-licensing arrangements with other manufacturers? If so, are responsibilities for responding to requests clearly documented?

3) Assess where your serialized data is being stored and maintained. Is it accessible for real time verification requests? Does your company currently have an automated process in place, which is necessary based on volume?

4) Have you communicated what method you plan to use to verify saleable returns with your wholesale distributor?

5) Have you communicated how you will respond with positive and negative verification responses?

6) In the event of a failed verification request, have you identified who your wholesale distributor should direct a communication to? Have you communicated this information to your trading partner?

For distributors:

1) Has your company determined how it will conduct saleable returns verification requests? Will you be building a solution or utilizing a solution provider?

2) If utilizing a solution provider, have you communicated your business requirements to them?

3) Have you communicated what types of verification processes your company intends to support?

4) Have you communicated how you will act on positive and negative verification requests?

5) In the event of a failed verification request, have you identified who to direct communication to?

Call to Action

Distributors

— Determine level of integration required with your internal systems. Consider factors such as return volume and frequency.

— Conduct discussions with your trading partners to mutually understand the impact and the planned solution.

— Continue testing and implementing receipt of serialized PI data from the manufacturer/manufacturer 3PL as they become capable.

Manufacturers

— Know your products and your responsibilities, i.e. co-licensing, divestiture— who is on point to respond to verification requests?

— Talk to your solution provider and understand their plans and capabilities, i.e. how will they be supporting the industry with meeting verification requirements?

— Conduct discussions with your trading partners to mutually understand the impact and the planned solution.

Solution Providers

— Clearly define and communicate the scope of your solution moving forward: a) to create/ route verification requests/ responses; b) to accept requests and respond as manufacturer's serial number repository; or c) to support both.

— Update your product roadmap and confirm alignment to the timeline for testing and production readiness.

— Meet with your current customers to confirm their needs and share your plans.

Verification Router Service Task Force Participating Companies

- » AbbVie US
- » Accenture
- » Acsis, Inc.
- » Adents
- » Akorn Pharmaceuticals
- » Allergan
- » Amgen Inc.
- » AmerisourceBergen Corporation
- » Amneal Pharmaceutical
- » Apotex Corp
- » Antares Vision North America, LLC
- » Arvato Systems N.A
- » Astellas Pharma US, Inc
- » AstraZeneca Pharmaceuticals LP
- » Authentag
- » Axway
- » Bausch + Lomb
- » Baxter Healthcare
- » Beatus Pharmaca Pharmaceuticals, Inc
- » Bell & Howell LLC
- » Boehringer Ingelheim Pharmaceuticals, Inc.
- » BrandSure, LLC
- » Bristol-Myers Squibb Company
- » BTG
- » Cardinal Health, Inc.
- » Chronicled
- » Cognizant Technology Solutions

- » CVS Health
- » DreamWeaver LLC
- » Dr. Reddy's Laboratories, Inc.
- » Eisai, Inc.
- » Enterprise System Partners Global Corporation
- » Excellis Health Solutions
- » EVERSANA
- » FedEx Supply Chain
- » Fresenius Kabi
- » Frequentz, Inc.
- » Genentech, A Member of the Roche Group
- » Gilead Sciences, Inc.
- » GlaxoSmithKline
- » GS1 US
- » GSMS, Inc.
- » Inmar
- » Johnson & Johnson
- » KNAPP Inc.
- » Kowa Pharmaceuticals America, Inc
- » KPMG LLP
- » Lilly USA, LLC
- » LSPediA
- » McKesson Corporation
- » Merck & Co., Inc.
- » Morris & Dickson Co., L.L.C
- » Movilitas Consulting
- » Mutual Drug

- » Mylan Inc.
- » Novartis Pharmaceuticals Corporation
- » Novo Nordisk Inc.
- » Optel Group
- » Otsuka America Pharmaceutical, Inc.
- » Paragon Consulting Services, Inc.
- » Pfizer Inc
- » Purdue Pharma L.P.
- » rfXcel
- » RxCrossroads by McKesson
- » Sagent Pharmaceuticals, Inc.
- » Sanofi US
- » SAP SE
- » Smith Drug Company
- » SunGen Pharma LLC

- » Sunovion Pharmaceuticals Inc.
- » Systech International
- » TraceLink Inc.
- » UCB Pharma, Inc.
- » Vormittag Associates, Inc.
- » ValueCentric, LLC
- » Value Drug Company
- » Verify Brand, LLC
- » Verizon Enterprise Solutions
- » WDSrx – Woodfield Distribution, LLC
- » Xyntek Inc.

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