The FDA DSCSA Pilot Program

Router Service Solution for Verification/Notification and Interoperability 2023

FINAL REPORT

V1.4

Contents

1 SUMMARY

The U.S. Food and Drug Administration (FDA) is establishing the Drug Supply Chain Security Act (DSCSA) Pilot Project Program to implement section 582(j) of the FD&C Act. This program is intended to assist the FDA and members of the pharmaceutical distribution supply chain in developing an interoperable electronic system to be established by 2023. The 2023 system has the potential to reduce the diversion of drugs distributed domestically and help keep counterfeit drugs out of the supply chain. The pilot program will explore issues related to utilizing a product identifier for product tracing, improving the technical capabilities of the supply chain, identifying the system attributes necessary to implement the DSCSA requirements, and any other issues identified by the FDA (see section 582(j)(2)(B) of the FD&C Act).

Through our Verifier® Verification Router Service (VRS) solution, LSPediA has developed an exceptionally cost-effective way to use product identifiers for verification that deters counterfeits. The Healthcare Distribution Alliance (HDA) has already tested and recommended VRS technology for solution providers, wholesalers, and manufacturers. LSPediA is one of the first providers participating in the HDA tests, having performed more than 100,000 drug verifications so far.

Recognizing that VRS and, more importantly, the technology that enables VRS, can expand beyond verification to conduct product tracing and create interoperability, LSPediA seeks to participate in the FDA DSCSA Pilot Project Program for Verification/Notification and Interoperability. The results of this testing will demonstrate that VRS is the most viable path to full DSCSA compliance and can be put in place by trading partners in accordance with the 2023 deadline.

2 ABOUT LSPEDIA

LSPediA is a leading provider of services and solutions that secure supply chains, protect against product counterfeiting, and help businesses comply with FDA regulations. Our customers are pharmaceutical manufacturers, re-packagers, wholesale distributors, and dispensers. LSPediA helps customers define their needs and implement best-of-breed supply chain and enterprise solutions that improve efficiency and comply with both FDA and global standards.

As one of the original participants in the HDA's VRS pilot program, LSPediA's serialization solution is the first one specifically engineered to meet DSCSA requirements. The LSPediA VRS was designed and developed by top pharmaceutical supply chain subject-matter experts to enable trouble-free verification, compliance process, workflow, reporting, and documentation.

LSPediA has years of experience in the pharmaceutical industry and across the pharmaceutical supply chain. We have been involved in serialization projects for more than 10 years in the U.S., Europe, and Asia, working for some of the largest and smallest pharmaceutical companies, third-party logistics providers, and wholesalers. LSPediA is well positioned to conduct a successful DSCSA pilot to demonstrate a path to interoperability that is robust, practical, and easily implemented by the largest as well as the smallest companies working in the pharmaceutical supply chain.

3 PARTNERING ENTITIES

LSPediA proposed that a pilot program involve both large and small companies, and include manufacturers, wholesalers, and dispensers. The partnering entities in this pilot project are:

- LSPediA Inc.
- Kowa Pharmaceuticals America, Inc
- Ingenus Pharmaceuticals, LLC
- Auburn Pharmaceutical Co
- AmerisourceBergen Corp
- Smith Drug Company
- SpartanNash Company

4 EVALUATION METHOD

4.1 PRODUCT IDENTIFIER (PI)

The pilot performed live verification testing at the locations of wholesale distributor and dispenser participating partners (Requestors). Verification was performed by scanning the product identifier (PI) imprinted or affixed to each drug product package or cases.

A PI is consisted for four data elements:

- NDC
- Serial number
- Expiration date
- Lot number

DSCSA requires the PI to be displayed in drug packages and their homogeneous cases. The PI contains the human readable data and the barcode that is embedded with the same data. The PI data elements are circled in the sample label blow.

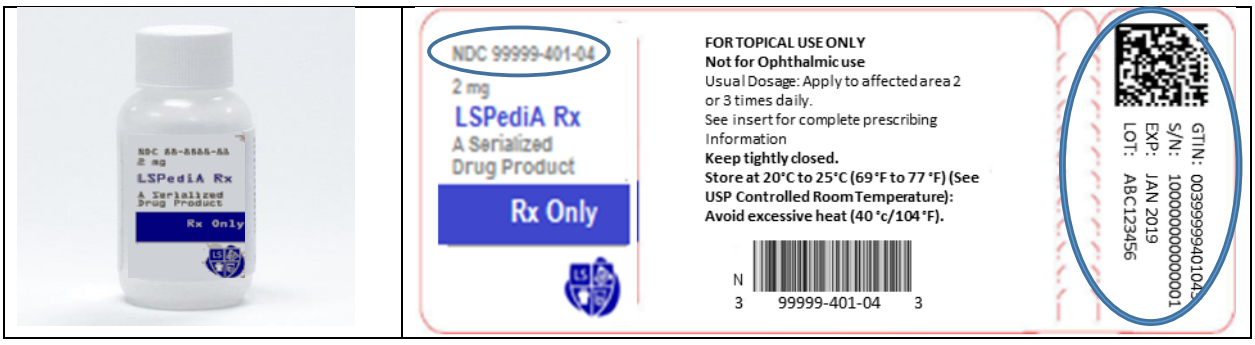


Figure 1 Example of Product Identifier on a Drug Package

The US pharmaceutical industry has widely adopted the GS1 standard for barcode formatting. The above 2D barcode in the label example is a standard GS1 2D data matrix barcode.

4.2 GS1 2D Data Matrix Barcode [1]

The serialized drug packages in the US are imprinted or affixed with the GS1 2D Data Matrix Barcode (Barcode). Barcode is encoded with 4 data elements. They are Global Trade Identification Number (GTIN), serial number, expiration date, and the lot number. The GTIN contains the NDC but is not the NDC.

4.3 Verification Router Service (VRS)

This pilot uses LSPediA's VRS solution call OneScan to perform barcode scan, data collection, and business transactions. This pilot participants use OneScan to scan the Barcode on packages and homogenous cases. By parsing the data elements from Barcode, OneScan performs transactions including product verification, product investigation, and product status change, and interoperability. This pilot simulated verification of returned packages by having requestors scan on-hand live inventory in their distribution centers. The pilot also simulated negative verification mock drug packages (seed bottles). The seed bottles are made by LSPediA and shipped to the requestors.

4.4 Requestor and Responder Roles

In a verification transaction, Wholesale distributor and dispenser participants took the role as Requestor. They scan the Barcode, and OneScan automatically send verification or investigation requests to manufacturers. Manufacturer participants took the role as Responder. Upon a verification request from the requestor, OneScan delivers the 4 data elements parsed from the Barcode to the Responder's VRS system. The Responder's serial data repository system then searches for a match and provides an automatic response to the Requestor.

4.5 Pilot Process

The pilot was designed for participants to perform the following transactions:

- Requestors would scan live packages in the warehouse to simulate live verifications
- Upon a negative verification, the corresponding Responder would receive an email notification alerting them that a package failed the verification. This is an automatic process in OneScan.
- Requestors would scan live packages to simulate live interoperability by scanning a PI and retrieve the transaction information and transaction statement from the responder.
- All participants would collaborate in the investigation of suspect products using the seed bottles
- All participants would collaborate in the handling of illegitimate products using the seed bottles
- LSPediA would compile all data collected and report the analytics
- LSPediA would collect comments and feedback from all participants
- LSPediA would receive feedback from the FDA DSCSA Pilot Program team
- LSPediA would make recommendations to Participants the recommends DSCSA compliance process for verification, suspect product / illegitimate product handling, 3911 reporting, and interoperability.

[1] https://www.gs1.org/docs/barcodes/GS1_DataMatrix_Guideline.pdf

The above transactions including verification request, response, investigation, transactions are collected and maintained in OneScan.

5 GOALS AND OBJECTIVES

LSPediA proposed using OneScan to meet verification, notification, and interoperability obligations of companies operating under the DSCSA. The scope included end-to-end testing with participating trading partners. The goal of the pilot program was to use the product identifier to effectively meet DSCSCA requirements by performing the following operations:

- Verify product identifiers of returned products, allowing them to be resold
- Verify product identifiers of recalled the products and quarantine the recalled products
- Verify suspect products to deter counterfeiting
- Notify the FDA and trading partners of suspect products
- Conduct investigations using the unique product identifier
- Submit notifications in form 3911 to the FDA for suspect/illegitimate product investigation
- Perform interoperability by retrieving the serial product trace using product identifier data

6 PRODUCTS FOR THE PILOT PROJECT

6.1. PRODUCTS TO PERFORM VERIFICATIONS

LSPediA and participating partners performed the pilot program testing with live products in the warehouse to understand the state of partner inventory labeling for GS1 Label Compliance.

The product list is in Appendix A. In addition to the products listed in Appendix A, seed bottles were shipped to the wholesale distributors and dispensers in order to test exception scenarios and resolution activities.

6.2. PRODUCTS TO PERFORM NEGATIVE VERIFICATIONS

LSPediA shipped pilot kits containing mock bottles for negative verification to participating partners. Each kit included 20 bottles, organized into two sets of 10 bottles each. Each set represented a participating manufacturer. Nine of the 10 bottles in each set simulated different verification scenarios. The scenarios are listed below.

Bottle #	Verification Scenario	Verification Code
1	Positive verification	200 Verified
2	Positive verification, product with recall status	200 Verified Recall – Source manufacturer's recall notification
3	Positive verification, product with recall status	200 Verified Recall – Source FDA Recall Database
4	Negative verification	200 Not Verified – No Match GTIN Serial

5	Negative verification	200 Not Verified – No Match GTIN Serial Lot
6	Negative verification	200 Not Verified – No Match GTIN Serial Exp
7	Negative verification	200 Not Verified – No Match GTIN Serial Lot Exp
8	Product not found	404 GTIN not in VRS network
9	Positive verification, product with suspect status	200 Verified Suspect

Bottles 2 and 10 in each set were also used to simulate interoperability and verification security. The results are below.

Bottle #	Scenario	Explanation
2	Security	When the same product identifier was scanned by two or more different users in different locations within a short period of time, the system blocked the corresponding users from accessing the system.
10	Interoperability	Upon scanning of the product identifier, the system displayed transaction information and a transaction statement.

Other error codes, for example Error Code 500, are documented in Appendix E.2. They are not in scope for this pilot.

Mock bottles from the pilot kits

Honeywell Voyager 1452G 2D Kit

7 PILOT PROGRAM TIMELINE AND PROGRESS

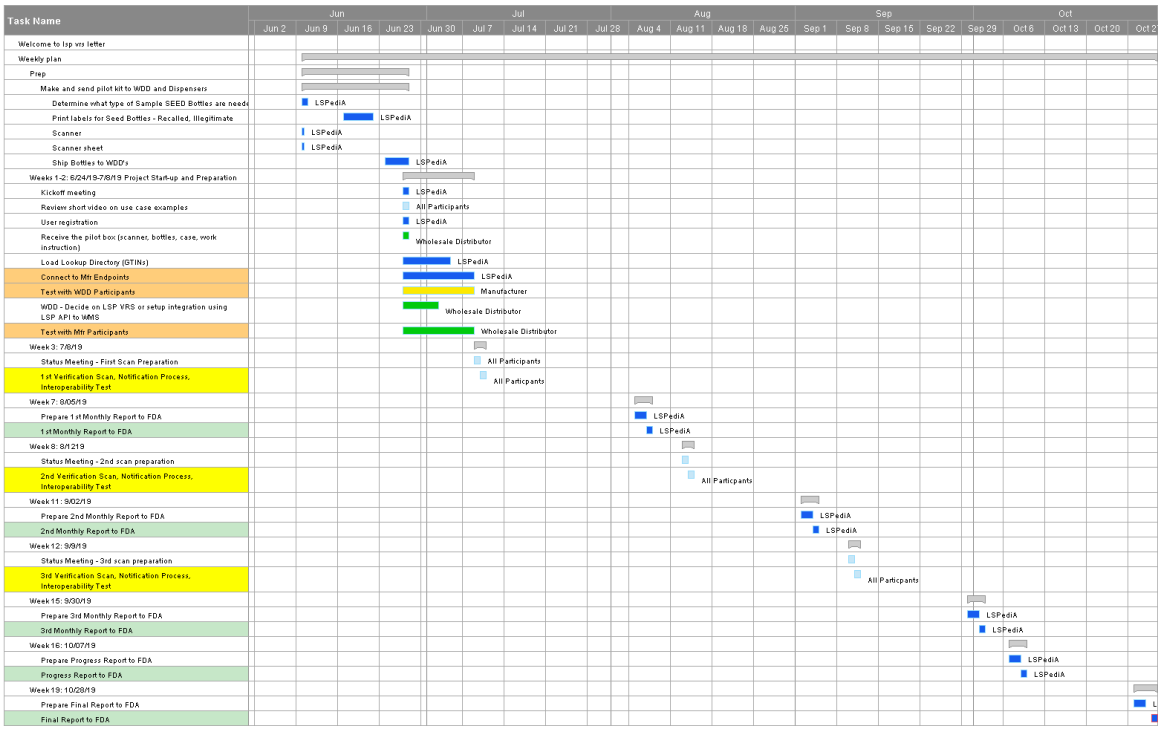
7.1. PILOT MILESTONE DATES

LSPediA started the pilot program on June 27, 2019 and completed it on October 31, 2019. The pilot milestones are listed in the table below.

Week	Project Tasks	Assigned to
06/27/2019	Project start-up and preparation	LSPediA, Requestors
07/10/2019	Kickoff of training meeting	LSPediA, Partners, FDA
07/17/2019	First verification scan, notification process, interoperability test	LSPediA, Partners, FDA
08/07/2019	First monthly report to FDA	LSPediA, FDA
08/14/2019	Second verification scan, notification process, interoperability test	LSPediA, Partners, FDA
09/04/2019	Second monthly report to FDA	LSPediA, FDA
09/11/2019	Third verification scan, notification process, interoperability test	LSPediA, Partners
10/02/2019	Third monthly report to FDA	LSPediA, FDA
10/29/2019	Progress report to FDA	LSPediA, FDA
10/31/2019	Project completed	LSPediA, partners
02/07/2020	Final report to FDA	LSPediA, FDA

7.2. PROJECT PROGRESS

A project plan is being shared with participants and the FDA via a Smartsheet that all participants will have access to view. It covers all the activities that occurred during the pilot program. A sample is shared below.



Below is a list of all pilot tasks and their start and end dates.

Task Name	Status	Duration	Start	Finish
Welcome to LSPediA VRS letter	Complete			
Weeks of 6/24/19 - 7/05/19: LSPediA prep	Complete	20d	06/10/19	07/05/19
Make and send pilot kit to WDD and dispensers	Complete	15d	06/10/19	06/28/19
Receive the pilot box (scanner, bottles)	Complete	1d	07/05/19	07/05/19
Kickoff	Complete	13d	06/28/19	07/16/19
Kickoff meeting	Complete	1d	06/28/19	06/28/19
User registration	Complete	5d	07/10/19	07/16/19
Standing Meeting—first group meeting	Complete	1d	07/10/19	07/10/19
Training	Complete	1d	07/10/19	07/10/19
Review short video on use case examples	Complete	1d	07/10/19	07/10/19
Distribute VRS user IDs	Complete	1d	07/12/19	07/12/19
SharePoint file share for all documents	Complete	1d	07/10/19	07/10/19
Round 1	Complete	6d	07/16/19	07/23/19
Weekly open office	Complete	1d	07/16/19	07/16/19
Standing meeting—first scan preparation	Complete	1d	07/17/19	07/17/19
First Verification Scan	Complete	5d	07/17/19	07/23/19
First report drafted	Complete	5d	08/01/19	08/07/19
First report to FDA	Complete	0d	08/07/19	08/07/19
Standing meeting – second group meeting	Complete	1d	08/14/19	08/14/19

Second verification scan, notification process	Complete	10d	08/14/19	08/29/19
Second report drafted	Complete	5d	08/25/19	08/29/19
Second report to FDA	Complete	0d	09/04/19	09/04/19
Third report drafted	Complete	5d	09/27/19	10/01/19
Third report to FDA	Complete	0d	10/02/19	10/02/19
Progress report to FDA	Complete	0d	10/29/19	10/29/19
Final report to FDA	Complete	30 days	11/14/19	02/07/2020

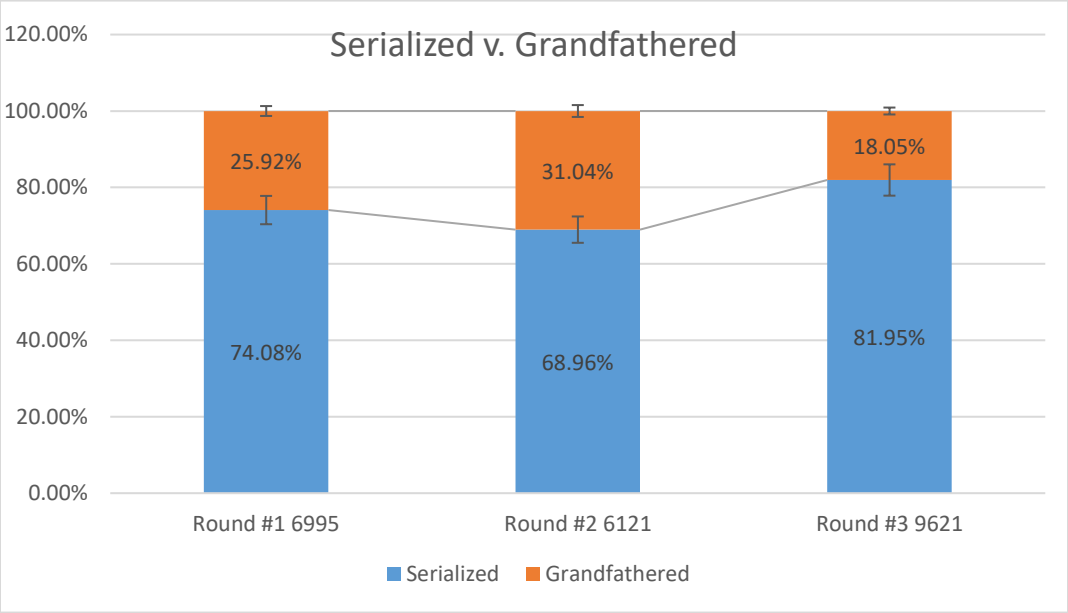
8 TRENDING

The pilot was planned for a total of three rounds of warehouse and seed bottle scans. Each round had shared objectives in collecting warehouse serialization data and advancing through planned verification scenario testing.

8.1 TRENDING REPORT

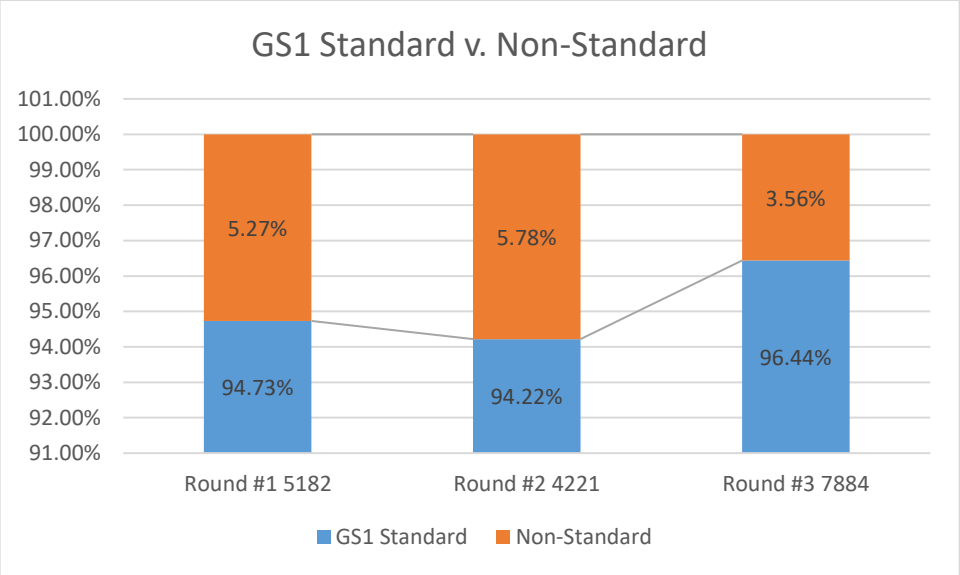
The three rounds of warehouse scans sampled 6,995, 6,121, and 9,621 packages, respectively. When the collected data was compared for trending analysis, we found performance improvement across all categories.

8.1.1 Serialized Packages v. Grandfathered Packages



8.1.2 GS1 Standard v. non-Standard

In the three rounds of data collections, 5,182, 4,221, and 7,884 packages were serialized, respectively. Among the serialized packages, we analyzed the product identifier's 2D barcode for conformance to GS1 standard. We found consistency between rounds 1 and 2, and improvement in round 3.

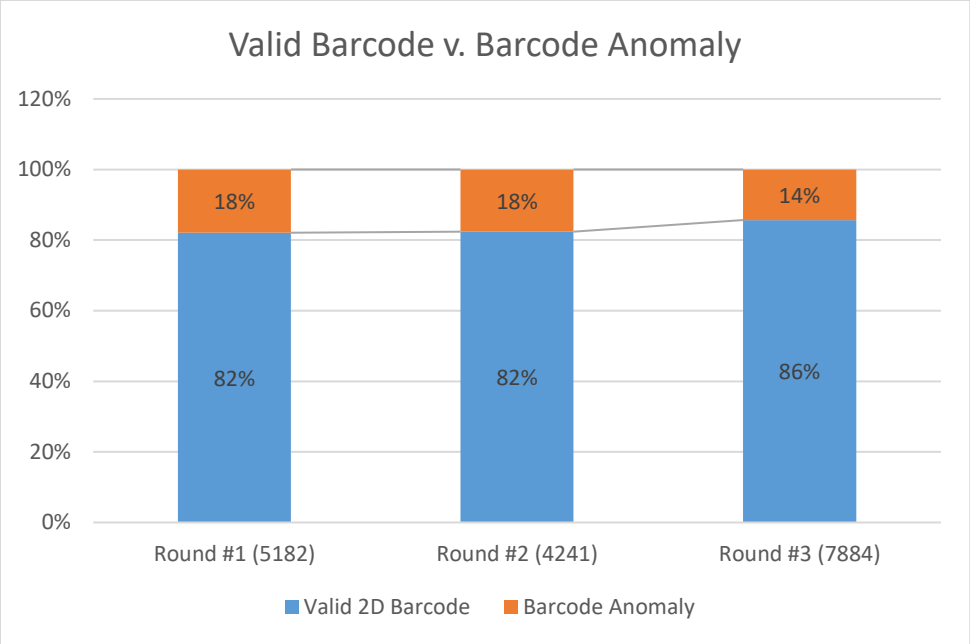


8.1.3 Valid Barcode v. Barcode Anomaly

A serialized barcode that meets GS1 standard does not mean it processes successfully. For example, GS1 standard allows "00" date encoding, so coding 11/00/2019 into the date element of the GS1 2D data matrix meets GS1 standard. But in the real word, computer system and database standards don't allow "00" dates. When a scanner meets a barcode with a 11/00/2019 date and transmits it to the computer system, the computer system will error out. The reason is that 11/00/2019 is not a valid date format by any database standard.

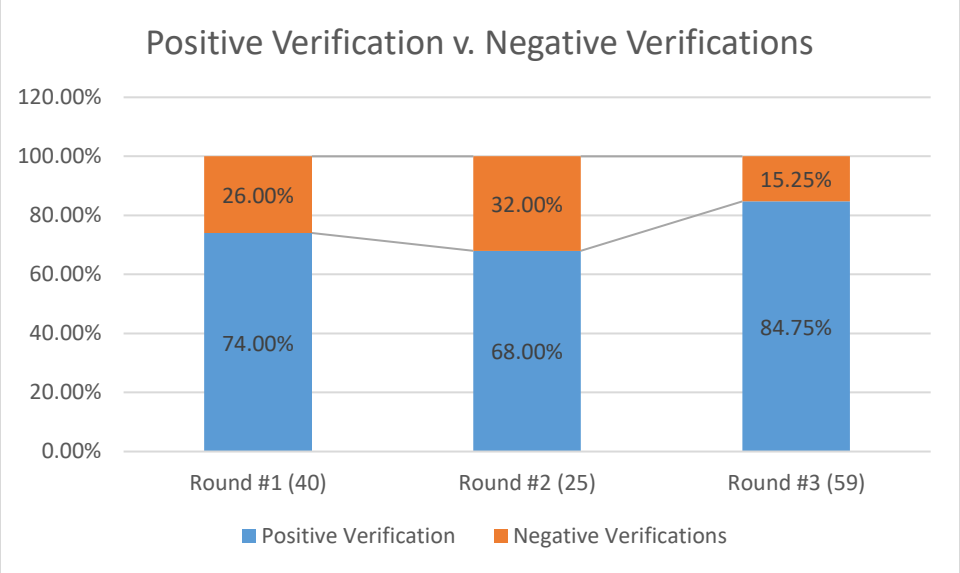
Because a barcode with "00" dating can't be processed, it will result in a negative verification. Likewise, barcode parsing and barcode coding errors can also lead to negative verification. We group all barcodes that can't be processed for the above reasons in the "barcode anomaly" category. On the other hand, all barcodes that can be processed are in the "valid barcode" category.

Among the 5,182, 4,241, and 7,884 serialized packages in the three rounds of warehouse scans, 928, 747, 1,129 packages contained barcode anomalies. The pilot shows on average 16% to all barcodes contain anomalies.



8.1.4 Product Identifier Verification (live verification in warehouses and stores)

Among the warehouse scans, some participants had on-hand inventory of the products from the manufacturers. In three rounds of testing, 40, 25, and 59 such packages were scanned and verified, respectively. Their verification results are illustrated below.



8.2 Feedback and Lessons Learned

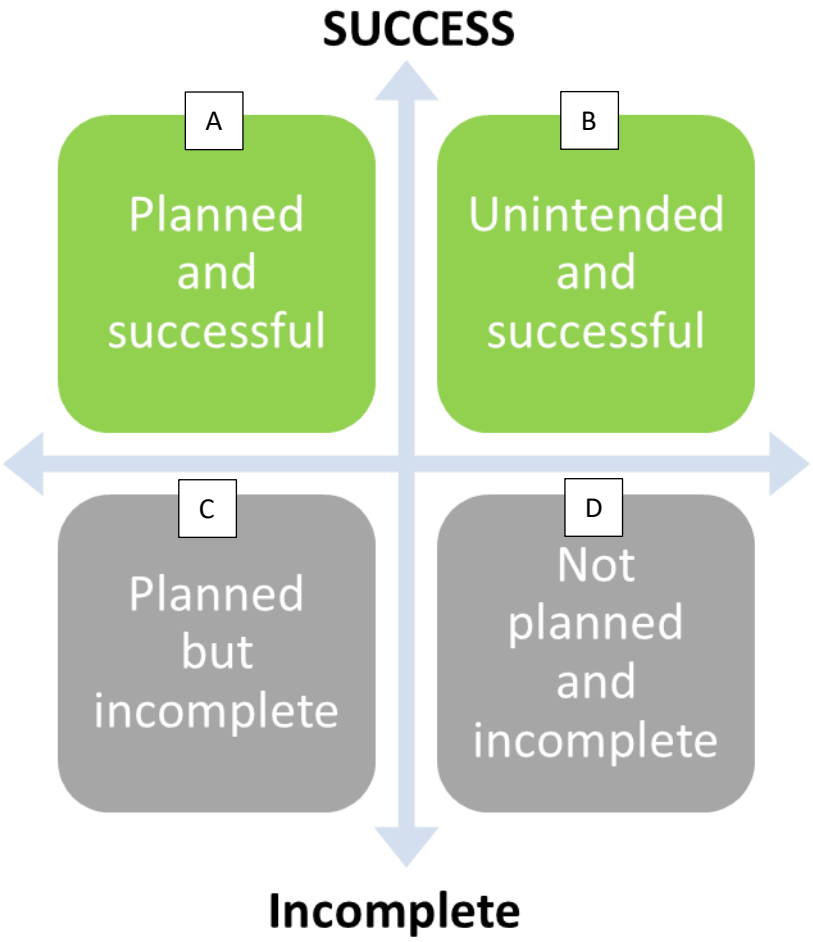
The pilot allowed for an end-to-end supply chain test in a live production environment with controlled settings. For all participants, this was the first time that they see serialized products travel from the beginning of the supply chain (manufacturer) to the end of the supply chain (dispenser). OneScan serves as the vehicle, shared workspace, and the electronic database that enabled verification, interoperability, and data sharing. During the pilot, live products were verified and stocked. Seeded bottles were

recalled, quarantined, investigated, cleared, and reported on 3911. There were also challenges, questions, and new discoveries. The participants needed to, and gladly did, step out their silos to observe each other's operations, understand dependencies between trading partners, and gain insight into best practices that will ensure they work smarter and create value at every stage.

At the end of the pilot, the participants provided their feedback in four categories:

1. Planned and successful
2. Unintended and successful
3. Planned but incomplete
4. Not planned and incomplete

The four categories are illustrated in the chart below.



The detailed feedback is summarized below.

8.2.1 LSPediA Pilot Summary

A. Planned and successful

1. Pilot deliverables and mechanics
    A. Three rounds of seed bottle testing
    B. Warehouse scans
    C. Data and FDA reporting
    D. Great participation and collaboration from everyone
    E. Great interactive sharing and discussion during weekly office hour sessions
2. Performed end-to-end product verification using unique product identifier.
3. Identified critical points in the supply chain where a product should be verified.
4. Automated the identification and management of negative verifications, and minimized manual investigative resource and efforts.
5. Facilitated collaborative investigations with full audit trails and created a single-source-of-truth workspace amongst partners.
6. Showed value in the ability to efficiently manage exceptions and "rescue" products with negative verifications due to barcode anomalies – keeping them viable for supply chain continuity and availability to patients.
7. Mitigated regulatory risk with an ability to successfully identify, quarantine, investigate, and report suspect and illegitimate products.
8. Ratified the suspect product investigation process flow and illegitimate handing process flow with participants.

B. Unintended and successful

1. Collected samples of diverse package labels; created valuable training materials for the warehouse operator to identify and scan the right 2D barcode on packages.

C. Planned but incomplete

1. Other manufacturers who are not in the LSPediA Pilot have not turned on their Production VRS system, so we were unable to verify their products during the pilot.

D. Not planned and incomplete

1. Operator moved to scan an item too quickly before the previous scan was committed, causing some unlogged scan. (Following the pilot, LSPediA added a sound to OneScan that indicates a scan has been successfully committed.)

8.2.2 Wholesale Distributor Pilot Feedback

A. Planned and successful

1. Collected data and gained firsthand knowledge of our serialization status in the warehouse (grandfathered, barcode compliance, barcode anomaly, verification rate).
2. Achieved a greater understanding of VRS, the capability of the tracking program, and requirements placed upon us as wholesalers for compliance.
3. Successfully scanned all inventory in the warehouse and test bottles.
4. Tested scanners and smart devices provided by LSPediA.

B. Unintended and successful

1. Gained firsthand knowledge of the process from our perspective as the wholesaler and from the manufacturer's perspective in phase 3 (where we saw the process from beginning to end).
2. Developed 2D scanning best practices.

C. Planned but incomplete

1. Completed the entire warehouse scan of all RX, 2D, and linear barcodes – operator moved to scan the next before the previous scan was logged successfully. (After the pilot, LSPediA added a sound to signal that the scan logged.)

D. Not planned and incomplete

1. QR codes that appear on the top, bottom, and side of bottle that did not represent the GTIN were encountered, resulting in lost scans. As a result, an opportunity for training was identified.

8.2.3 Dispenser Pilot Feedback

A. Planned and successful

1. Gained a greater understanding of VRS and the requirements placed upon us as a duel supply chain partner: both a dispenser with thousands of corporate stores, and a wholesaler with hundreds of associated stores.
2. Successfully scanned test bottles.
3. Tested our new scanners and touch-screen computers recommended by LSPediA.
4. Discovered that the OneScan Process Flow Diagrams for suspect and illegitimate product are enormously helpful.

B. Unintended and successful

1. Gained firsthand knowledge of the process from our perspective and from the manufacturer's perspective (saw the process from beginning to end).

C. Planned but incomplete

1. None

- **Not planned and incomplete**

    2. QR codes that did not represent the GTIN were scanned instead of the correct code (insert, bottle, website, etc.).

8.2.4 Manufacturer Pilot Feedback

A. Planned and successful

1. Gained greater familiarity with the VRS system.
2. Vastly improved company employee awareness around VRS.
3. Successfully responded to system inquiries from partners during pilot.
4. Improved understanding of which internal departments should be involved in the future – flow charts very helpful.
5. Enabled improved understanding of LSPediA's OneScan system.
6. Formalized internal suspect-investigation process.

B. Unintended and successful

1. Tested internal serialization database and query capabilities.
2. Learned that we have more work to complete in order to finalize our future workflow.
3. Realized our VRS and DSCSA re-training needs were greater than expected.

C. Planned but incomplete

1. Integrated more company departments and employees in the VRS Pilot.
2. Learned that bundle and case barcodes had more issues than anticipated. The issue was resolved a few weeks after the pilot has completed.

D. Not planned and incomplete

1. Would like to have had accounting, QA, and regulatory all present to observe and learn about our trading partners' VRS inquiries and our responses.

8.3 LSPediA Pilot Recommendations

8.3.1 Trainings

The pilot found that drug packages contain various formats and barcodes. Proper training should be provided to give the operator the skills of recognize the correct barcode to scan. An example of the training material is enclosed in Annex 2.

In addition, the process of suspect product and illegitimate product requires collaboration and data sharing between the trading partners. OneScan has built in process flow and business rules to enforce the required steps are taken in process investigation and notification. OneScan training and Process training were provided multiple times in the pilot. The participants especially appreciated the clearly

documented process maps which provided guidance of the entire workflow and each personnel's responsibility individually.

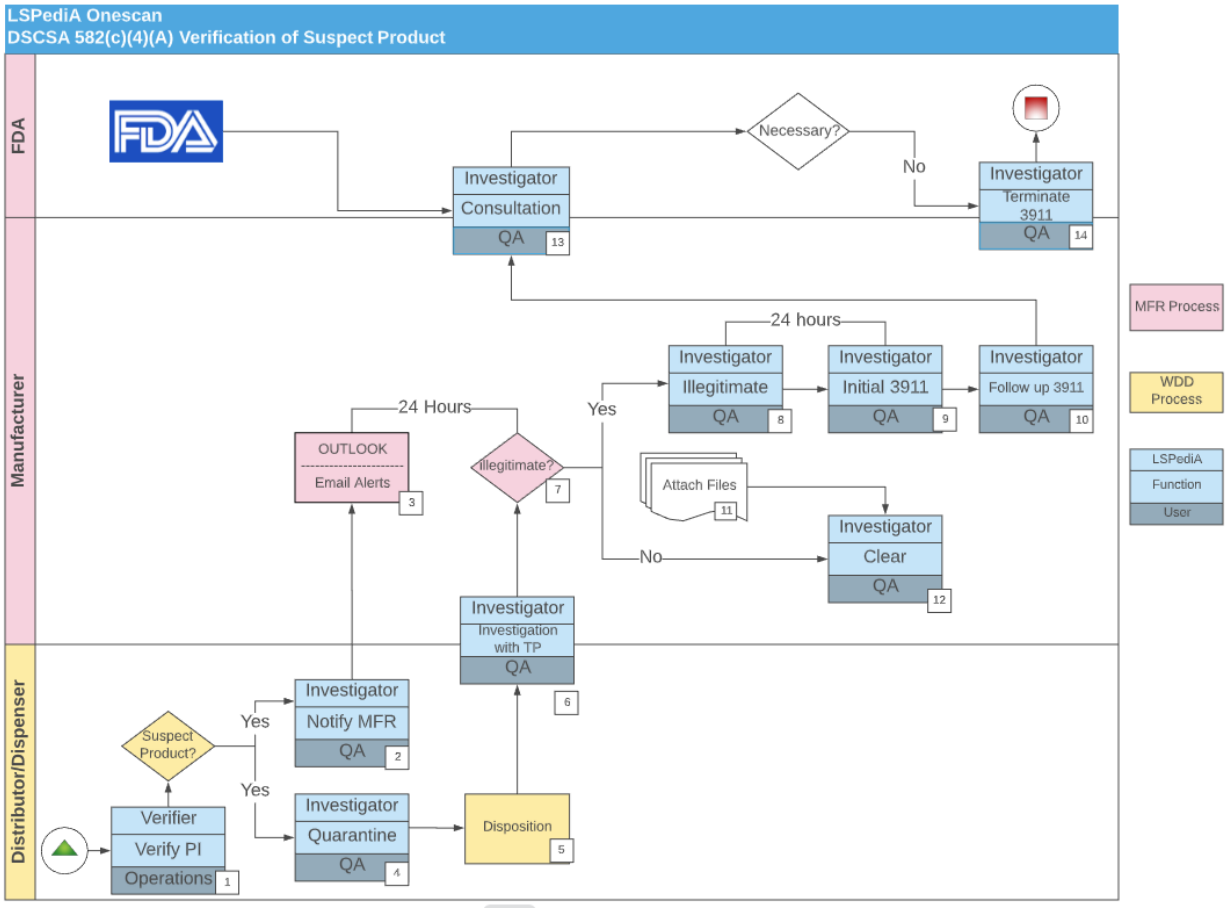
8.3.2 DSCSA Verification Requirement Process Maps

The DSCSA verification requirement is complex. Negative verifications, suspect product investigation, and illegitimate product verification impacts multiple internal departments as well as the relevant trading partners. To coordinate the response within the internal organization and respond to verifications properly to external partners takes clear definition of roles and responsibilities. The process maps LSPediA provided were well received. During the pilot, all participants contributed to the process maps with compliance and operational best practices.

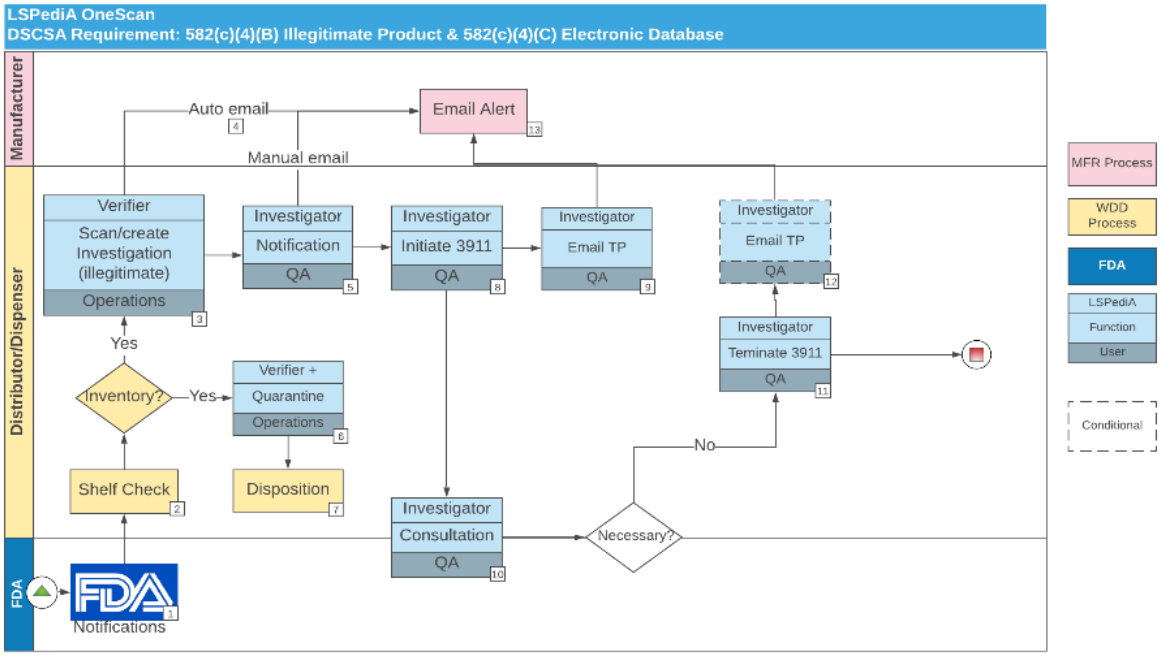
8.3.2.1 Process map – wholesale distributor verification requirement of suspect product

This process describes that a wholesale distributor encountered a suspect product. They then notify the manufacturer of the product.

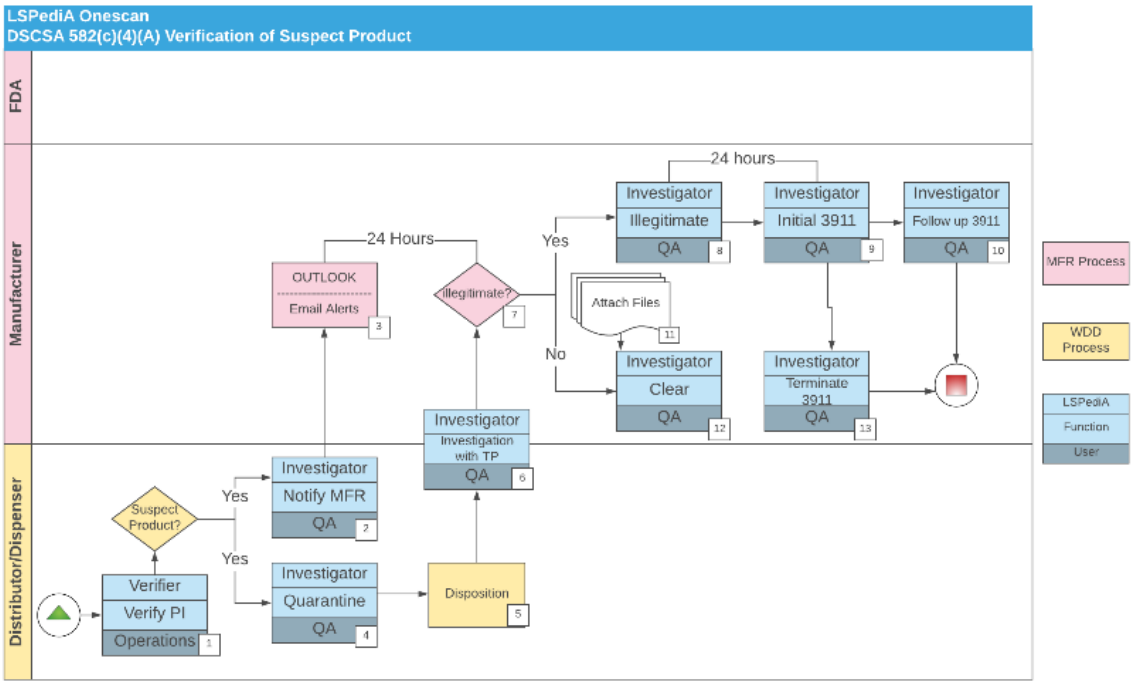
The manufacturer conduct investigation and determines if it is a good product or an illegitimate product. The manufacturer can clear the good product. If it is an illegitimate product, the manufacturer then reports to the FDA using the 3911 Form.



8.3.2.2 *Process map – wholesale distributor verification requirement of illegitimate product*



8.3.2.3 *Process map – wholesale distributor verification requirement for saleable returned product*



8.3.3 Verification Testing and Cutover to Production

Verifications can be performed by either EPCIS data exchange or VRS. Due to the readiness or lack of readiness of EPCIS data exchange, we recommend supply chain partners begin building or continue to build out capabilities for both.

We believe the flexibility of two methods, EPCIS and/or VRS, will allow trading partners to meet the current verification requirement and the interoperability requirement in 2023.

8.4 Verification of Suspect/Illegitimate Product Starting November 2019

Apply best practices for verification of suspect and illegitimate products in accordance to DSCSA section 582 (c)(4)(A) – (C). Keep records of verification request and verification response.

8.5 Verification of Saleable Returns November 2019 to November 2020

Test verifications: Test verifications should be performed for both EPCIS and VRS in a controlled test environment. Collaborate with trading partners to perform live scanning in a live warehouse environment and submit test data (see below) for system testing. Test transactions in the test system (not production) are test in nature. These transactions are not subject to 582 (c)(4)(D) requirement. Products that receive a false negative verification during this testing phase are considered "test of process" and not a "request for verification."

Production verifications: After being moved to a production environment following successful testing, when encountering a negative product notification, trading partners shall begin the coordinated investigation process.

8.5.1 Collaboration

8.5.2 Interoperability

The same technology for VRS applies well for interoperability. During the Pilot, dispenser and distributor participants LSPediA's Interoperability module to retrieve transaction information and transaction statement by a single scan of the PI. The EPC data in an EPCIS system is called EPC data.

8.5.3 Value Beyond Compliance

9 Pilot Summary

The Pilot used OneScan to meet verification, notification, and interoperability obligations of companies operating under the DSCSA. The scope included end-to-end testing with participating trading partners. The goal of the pilot program was to use PI on packages and cases to effectively meet DSCSCA requirements. At the completion of the pilot, the participants successfully achieved such goal and following objectives:

- Verified returned products (live inventory) using PI on the packages
- Verified recalled products (seed bottle) using PI on the packages, simulated quarantine process
- Verified suspect products (see bottle), used PI to document the investigation.

- Conducted investigations using the unique product identifier and shared investigation data with the trading partners
- Upon manufacturer's determination that the suspect products were illegitimate, the manufacturer participants drafted 3911 Notifications using OneScan.
- Perform interoperability by retrieving the serial product trace using PI

Because the illegitimate product notifications drafted in Form 3911 resulted from the seed bottles, the pilot did not submit 3911 notifications to the FDA.

10 Confidentiality Agreement

Annex 1 – Participants Feedback

PILOT FEEDBACK FROM PARTICIPANTS

Annex 2 - Warehouse Training for PI Scanning

Training Scanning Serialized Pharmaceutical Packages

Appendix 3 - Pilot Products

Labeler Name	Description	NDC	Package Level
Kowa Pharmaceuticals America, Inc.	Livalo, Pitavastatin Calcium, 1.045 mg/1 tablet, 90 tablet, film coated	66869-104-90	Item, bundle, case
Kowa Pharmaceuticals America, Inc.	Livalo, Pitavastatin Calcium, 4.18 mg/1 tablet, 90 tablet, film coated	66869-404-90	Item, bundle, case
Kowa Pharmaceuticals America, Inc.	Lipofen, fenofibrate , 50mg/1 capsule, 30 capsule	66869-137-30	Item, bundle, case

Kowa Pharmaceuticals America, Inc.	Lipofen, fenofibrate, 150mg/1 capsule, 30 capsule	66869-147-30	Item, bundle, case
Ingenus Pharmaceuticals	Metformin HCL Tabs 850mg/1, TABLET, FILM COATED, 500ct	50742-155-05	Item, case
Ingenus Pharmaceuticals	Cyproheptadine HCL Tab USP, 4mg/1, 100ct	50742-190-01	Item, case
Ingenus Pharmaceuticals	Betamethasone Foam 0.12%, 100gm	50742-315-01	Item, case
Ingenus Pharmaceuticals	Betamethasone Foam 0.12%, 50gm	50742-315-50	Item
Ingenus Pharmaceuticals	Acetazolamide ER Caps 500 mg, 100ct	50742-233-01	Item, case
Ingenus Pharmaceuticals	Metoprolol ER Tabs 25mg, 100ct	50742-615-01	Item, case
Ingenus Pharmaceuticals	Nifedipine ER Tabs 30mg, 100ct	50742-620-01	Item, case
Ingenus Pharmaceuticals	Nifedipine ER Tabs 30mg, 100ct	50742-620-01	Item, case
Ingenus Pharmaceuticals	Nifedipine ER Tabs 60mg, 100ct	50742-621-01	Item, case
Ingenus Pharmaceuticals	Nifedipine ER Tabs 90mg, 100ct	50742-621-01	Item, case
Ingenus Pharmaceuticals	Lamivudine Tabs 150mg, 60ct	50742-622-01	Item, case
Ingenus Pharmaceuticals	Lamivudine Tabs 300mg, 60ct	50742-623-60	Item, case

APPENDIX 4. GLOSSARY OF TERMS

Term or Acronym Definition	
API	Application Program Interface
Authenticate	The practice of checking a Unique Identifier against a set of captured serialized data to determine its authenticity
Connection Information	A general term used in this document to refer to the technical information (e.g. end-point URL, security certificates, authentication parameters) needed to establish connection with the responder's repository.
DSCSA	Drug Supply Chain Security Act, Title II of the DQSA
Electronic Product Code Information Services (EPCIS)	Electronic Product Code Information Services (EPCIS) is a GS1 EPC global standard designed to enable EPC-related data sharing within and across enterprises. This data sharing is aimed at enabling participants in the EPC global Network to obtain a common view of the disposition of EPC-bearing objects within a business context. more at www.epcglobalinc.org
Expiry	Date of expiration or the last day the item should be used.

GCP	Global Company Prefix, a unique GS1 identification code for your company obtained through GS1.
GLN	Global Location Number, a 13-digit number created by a GS1 Company Prefix, a Location Reference and a Check Digit. A Global Location Number (GLN) is used to identify any location (physical or legal) that needs to be uniquely identified for use in the supply chain. The GLN makes possible the unique and unambiguous identification of physical locations and legal entities used in the supply chain.
GS1	GS1 (www.gs1.com) is a global organization dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility of supply and demand chains globally and across sectors. The GS1 system of standards is the most widely used supply chain standards system in the world.
GS1 Data Matrix	A two-dimensional matrix barcode consisting of black and white "cells" or modules arranged in either a square or rectangular pattern. The information to be encoded can be text or raw data. Usage granted to organization members of GS1.
GTIN (Global Trade Item Number)	An identifier for trade items developed by GS1. Such identifiers are used to look up product information in a database (often by inputting the number through a barcode scanner pointed at an actual product). The uniqueness and universality of the identifier is useful in establishing which product in one database corresponds to which product in another database, especially across organizational boundaries. Usage granted to organization members of GS1.
HDA (Healthcare Distribution Association)	HDA is the national association representing primary, full-service healthcare distributors. HDA member companies deliver more than nine million prescription medicines and healthcare products to more than 165,000 settings including chain and community pharmacies, hospitals, nursing homes, physician offices and clinics in every state and territory.
Item	The product secondary package; typically, a carton (Note: also referred to as smallest saleable unit)
LD	Look-up Directory (directory which contains the connectivity information of the Responder's repository fulfilling the verification request)
Manufacturer	Entity or organization responsible for packaging the product
Master Data	Core data that are essential to operations in a specific business or business unit
PI	"Product Identifier, defined by DSCSA as a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.
Provider	The entity providing access to the VRS Network through their own Verification Router Services
Repository	Repository refers to the Responder's systems that will minimally store the 4 PI data elements and provide the response to the verification request.
Requestor	Party that submits a verification request; for example, in the context of "dscsaSaleableReturn", a pharmaceutical wholesaler or distributor.

Requestor ID	A unique identifier assigned to Requestor entities that are registered and authorized to use the VRS.
Responder	Party that responds to a verification request; for example, in the context of "dscsaSaleableReturn", a pharmaceutical manufacturer or re-packager.
Responder ID	A unique identifier assigned to Responder entities that are registered and authorized to use the VRS.
S/N	Abbreviation for Serial number.
Serial Number	Character string that is given to a product in addition to a product number in order to differentiate the individual piece from all the other pieces.
Serialization Data	The group of data associated with the group of serialized items.
Serialized Global Trading Item Number (sGTIN)	The combination of a global trade identification number and serial number which uniquely identify an item.
SGLN	Serialized Global Location Number. Global location number after a URI codification format.
SKU	Stock Keeping Unit – Finished pack unit of dispense, the lowest level commercial pack.
SNI	Standardized Numerical Identifier, defined by DSCSA as "a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters." § 581(20).
Supply Chain Partner	Customer, supplier or partner that participates in the manufacturing, distribution and sale of products.
Transaction ID	A unique identifier assigned to requests that are initiated within the VRS.
Validation	Documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.
VRS Verification Router Service	VRS providers Solution providers that will provide Verification Router Services

LSPediA

About LSPediA

LSPediA provides SaaS solutions to the pharmaceutical industry. Manufacturers, wholesale distributors, dispensers, and healthcare providers partner with LSPediA to make, move, track, verify, and protect the drug products in their care for patient safety.

LSPediA is different because our solution potential is limitless. Built with user efficiency, automation, and data security at their core, our solutions are transforming compliance and supply chain efforts. LSPediA's OneScan, RxChain, and Investigator technologies enable error-free and keyboard-free capabilities for ASN, EPCIS, VRS, issue tracking, and interoperability.

For more information about our capabilities, call +1 (248) 973-2008, email info@lspedia.com, or visit our website at www.lspedia.com.