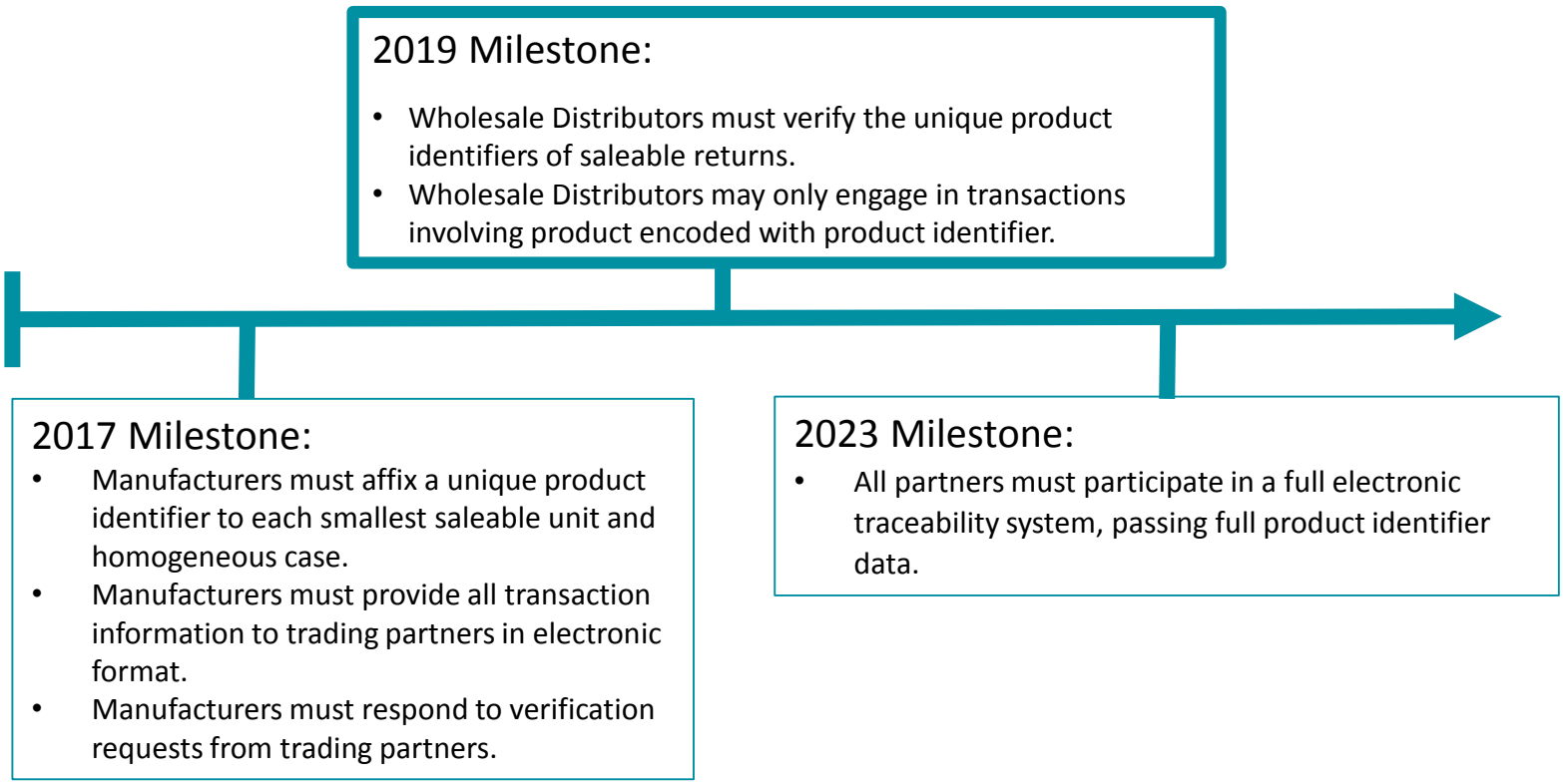
HDA DSCSA 2019 Compliance Scenarios

HDA

DSCSA Overview and Milestone Timeline

The Drug Supply Chain Security Act (DSCSA) takes effect over a 10 year period (from 2013 to 2023) and is punctuated by requirement milestones. The HDA pilot examined the 2019 milestone. The law requires that "Beginning [11/27/2019], upon receipt of a returned product that the wholesale distributor intends to further distribute, before further distributing such product, the wholesale distributor shall verify the product identifier, including the standardized numerical identifier…" for each sealed homogeneous case or on each package §582(c)(4)(D), §360eee- 1(c)(4)(D). An abbreviated version of the milestone timeline of this regulation between 2017 and 2023 is shown below.



The following pages detail the nine scenarios that were considered for compliance with the 2019 verification of saleable returns requirements.

Manufacturer sends purchased unit product identifiers to respective Wholesale Distributor (Scenario 1)

Steps

Manufacturer sends purchased unit product identifier information

Wholesale Distributor verifies product identifiers against internal database

Pilot Type

Live Pilot, Internal Solution

Description

- Manufacturers send aggregated product identifier information to each Wholesale Distributor for **ONLY** the units purchased by that Wholesale Distributor. The Wholesale Distributor stores these data in an internal database.
  - This is the only scenario which requires aggregation

- Upon receiving a saleable return, the Wholesale Distributor is able to reference an internal database comprised of the product data it received from the Manufacturer in order to verify the product identifier information.

Notes: _____

Manufacturer sends product identifiers for all units produced to Wholesale Distributor trading partners (Scenario 2)

Steps

Manufacturer sends product identifier information for all units

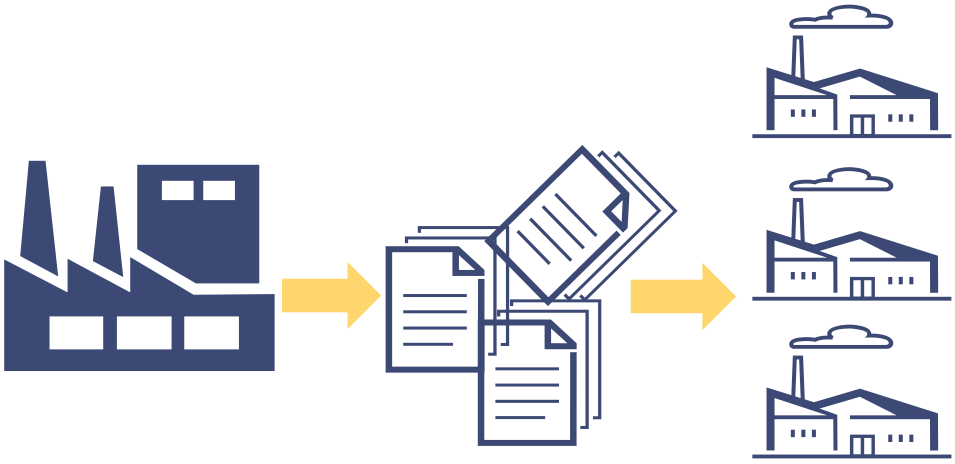
Wholesale Distributor verifies product identifiers against internal database

Pilot Type

White Paper Pilot

Description

- Manufacturers send product identifier information for **ALL** units shipped within the United States to every direct purchase Wholesale Distributor. The Wholesale Distributor stores these data in an internal database.



- Upon receiving a saleable return, the Wholesale Distributor is able to reference an internal database comprised of the product data it received from the Manufacturer to verify the product identifier information.

Notes:

Manufacturers send all data to central database that the Wholesale Distributors access for verification (Scenario 3)

Steps

Build a centralized database

Product information sent to central database

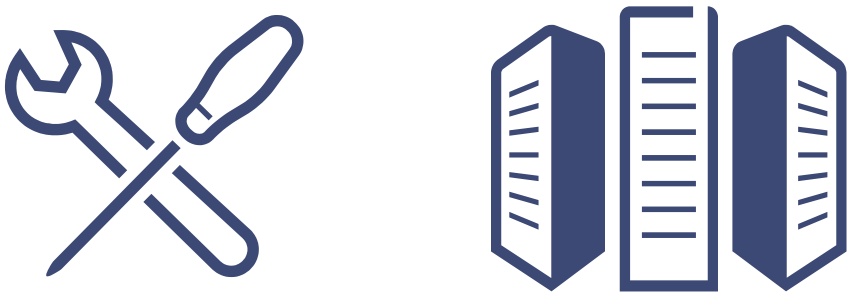
Verify product identifiers

Pilot Type

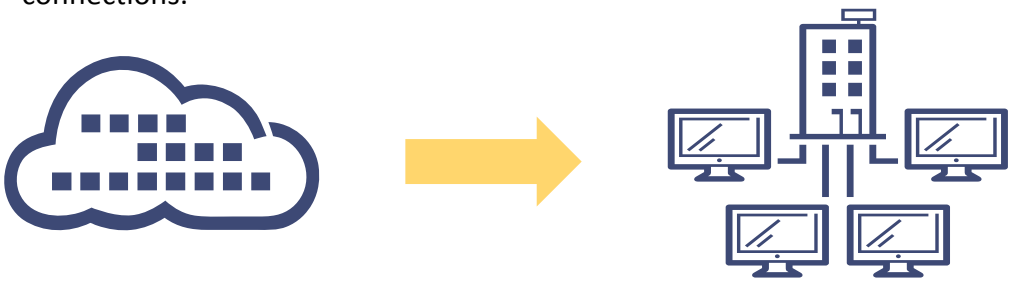
Live Pilot, External Solution

Description

- A centralized database houses all product identifier information.
- Point-to-point connections will be established from each Manufacturer and Wholesale Distributor to the centralized database.



- Manufacturers will send product information for all units shipped within the United States to the centralized database via point-to-point connections.



- Upon receiving a saleable return, Wholesale Distributors will verify the product identifier information against the central database.
  - The collection and parsing of data by the Wholesale Distributor can be executed manually or automatically via scanners with connectivity to the database.

Notes:

Wholesale Distributor builds point-to-point interface to Manufacturer database (Scenario 4)

Steps

Manufacturers build internal databases

Wholesale Distributors establish point-to-point connections with Manufacturers

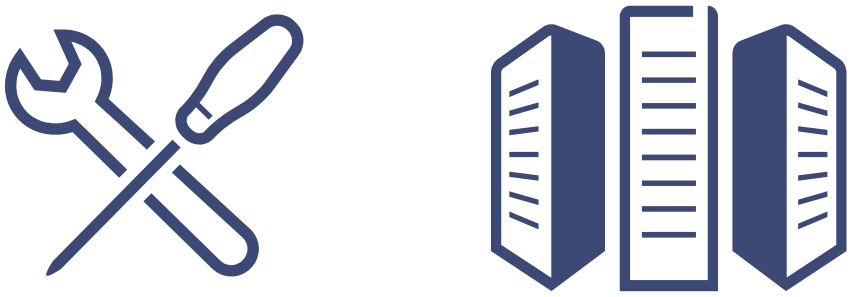
Verify product identifiers

Pilot Type

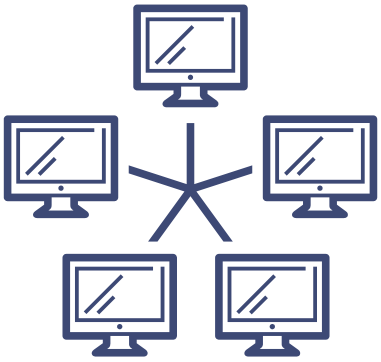
White Paper Pilot

Description

- Each Manufacturer stores its product identifier information in its own internal database.



- Each Wholesale Distributor builds and maintains a point-to-point connection with each Manufacturer's verification service.



- Upon the return of saleable products, Wholesale Distributors will use the point-to-point connections with Manufacturers to automatically verify product identifier information.

Notes: _____

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Wholesale Distributor accesses Manufacturer portal (Scenario 5)

Steps

Manufacturer builds internal database

Manufacturer builds portal access for Wholesale Distributors

Wholesale Distributors verify product identifiers through portal

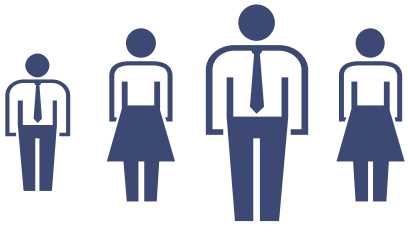
Pilot Type

Desktop Pilot

Description

- Each Manufacturer develops its own internal database to store all product identifier information.

- Each Manufacturer builds a portal and controls Wholesale Distributor access.
  - The Manufacturer's portal would be designed independently by each entity and the different portals may have a completely different look, interface, and operation, adding complexity for Wholesale Distributors.



- Wholesale Distributors query the Manufacturer's portal to verify the product identifier information for saleable returns.
  - This scenario requires a manual query of a specific Manufacturer's portal, rather than automatically routing the query to the appropriate Manufacturer database based upon a scan of the product identifier affixed to the product.

Notes: _____

Wholesale Distributor scans product on inbound and builds internal database for verification (Scenario 6)

Steps

Wholesale Distributor scans product on inbound receipt

Wholesale Distributor stores product identifier information

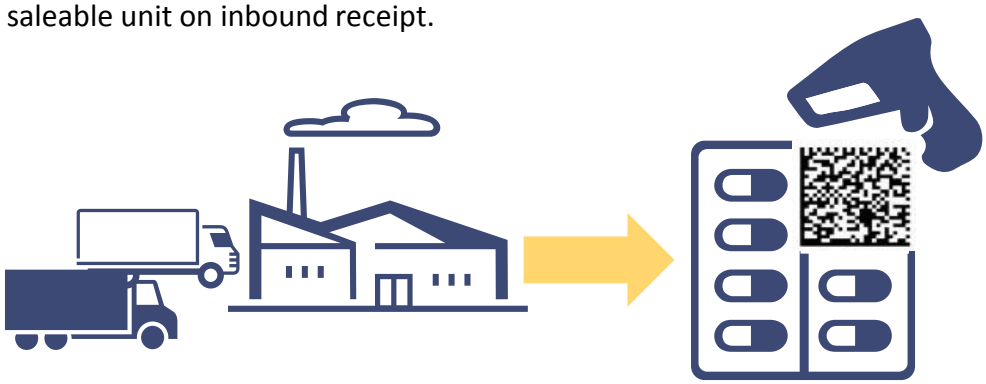
Wholesale Distributor verifies returns against its internal database

Pilot Type

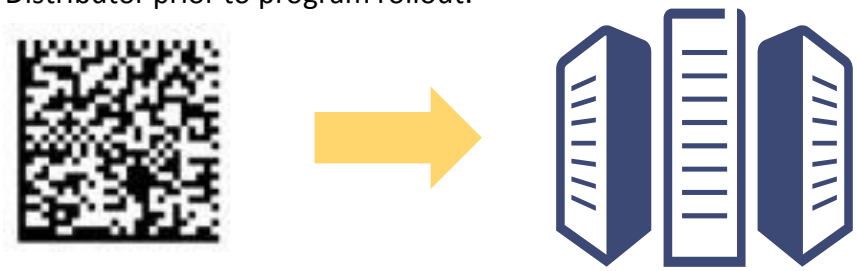
White Paper Pilot

Description

- Wholesale Distributor scans every product identifier at the smallest saleable unit on inbound receipt.



- Wholesale Distributor stores scanned product identifier information in an internal database.
  - The internal database must be developed by each Wholesale Distributor prior to program rollout.



- When products are returned, the Wholesale Distributor scans and verifies the product identifiers against its internal database.

Notes: _____

Wholesale Distributors scans product on outbound and builds internal database for verification (Scenario 7)

Steps

Wholesale Distributor scans product on outbound

Wholesale Distributor stores product identifier information

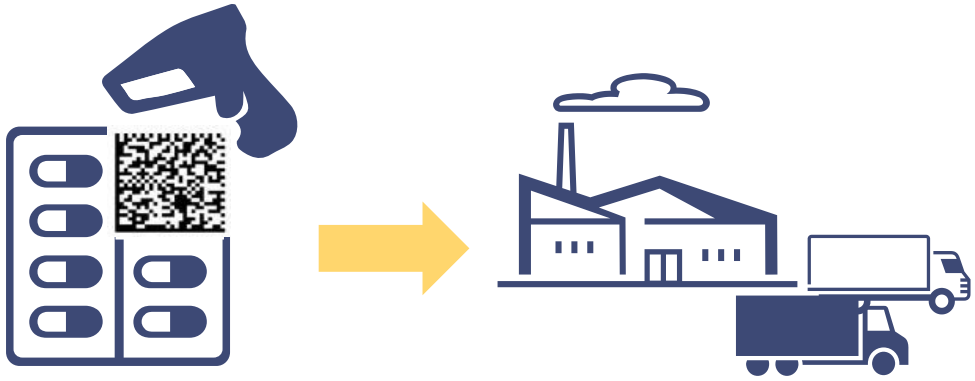
Wholesale Distributor verifies returns against its internal database

Pilot Type

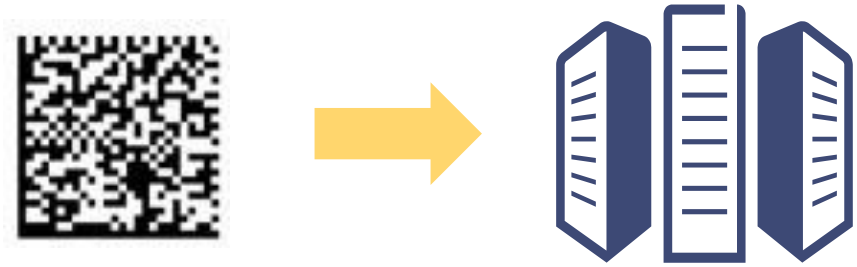
Live Pilot, Internal Solution

Description

- Wholesale Distributor scans the homogeneous case or smallest saleable unit product identifier on outbound.



- After the product identifier is scanned, the Wholesale Distributor stores all product identifier information in an internal database.



- As saleable products are returned, the Wholesale Distributor verifies the product identifier(s) against its internal database.

Notes: _____

Wholesale Distributor manually confirms with Manufacturers at time of return via phone or email (Scenario 8)

Steps

Product returned

Description

- Wholesale Distributor receives the returned serialized product.

Wholesale Distributor verifies by phone or email

- Wholesale Distributor contacts the Manufacturer via email or phone to verify the product identifier information.

Pilot Type

Desktop Pilot

Notes: _____

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Verification Router Service – Wholesale Distributor query is routed to appropriate Manufacturer database (Scenario 9)

Steps

Develop Verification Router Service

Returns verified through router

Pilot Type

Live Pilot, External Solution

Description

- A router service is built. It will return verification response utilizing connections with Manufacturers' databases.
  - Wholesale Distributors and Manufacturers build and maintain a single connection to the router instead of connecting with each individual trading partner.
  - All Manufacturer information continues to be held internally.

- The Wholesale Distributor captures the product identifier information and parses the data to the router service, which references the associated GTIN to automatically query the appropriate Manufacturer database and return a response in real-time.
  - Collection and transmission of the data can be done automatically by scanners which are connected to the database or performed manually.

Notes: