DSCSA Serialization End-to-End Proof of Concept Pilot

THE STUDY OF INTEROPERABILITY AND MOVING SERIALIZED PRODUCT ACROSS ALL SUPPLY CHAIN PARTNERS WITH A FOCUS ON THE IMPACT TO DISPENSERS

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SECTION 1: EXECUTIVE SUMMARY

The Food and Drug Administration (FDA) regulation contained in the Drug Supply Chain Security Act (DSCSA), Title II of the Drug Quality and Security Act, requires that the pharmaceutical industry implement end-to-end traceability by 2023. AmerisourceBergen Corporation and Xavier Health as contracted by AmerisourceBergen, led an end-to-end Proof of Concept (POC) pilot with the goal of demonstrating successful interoperable exchange of Transactional Information (TI), and Transactional Statement (TS) and evaluating the significant operational impact in a 2023 environment. The POC pilot was successful in providing necessary insight into where we are today and the challenges we face for successful 2023 implementation.

Successes

- Exchanged enhanced TI data, using GS1 EPCIS version 1.2, from nine manufacturers, including one using a third party logistics company.
- Transmitted enhanced TI data to a dispenser, using GS1 EPCIS version 1.2, to their third-party solution
- Demonstrated two different operational processes for "ensuring the receipt of TI"
- Provided, albeit manual, TI data to a dispenser using AmerisourceBergen's web portal and built out 2023 requirements to support automation.
- Gauged hurdles that would arise with a larger, full industry, 2023 implementation.

Challenges and Learnings

- Significant technical issues were encountered in attempting to implement a 2023 solution at the two dispenser facilities involved, resulting in the inability to scan for the planned four-week POC pilot.
- Rolling out necessary new tools took more time than expected. Given that the United States has 200,000 plus dispensers, being proactive in educating and implementing will be critical for success.
- Contingency time to address unanticipated issues, such as hospital network security and EPCIS exchange issues need to be built into any rollout plan.
- Current wholesaler IT solutions are built to only send TI data accompanied by the original TI receipt from the manufacturer. This could impact the ability to send TI data to the dispenser if product is in inventory at the wholesaler prior to November 27, 2023.

In summary, the engagement of manufacturing partners, wholesale distributors and dispensers (representing both a large hospital and a large chain pharmacy) was a significant accomplishment. All parties engaged in open dialogue from planning through pilot which resulted in essential learnings that will have a meaningful impact on 2023 practices.

As expected from previous pilots over the past three years, the exchange of enhanced TI went relatively smoothly from manufacturer to AmerisourceBergen. While the original plan was to have dispensers scan from the beginning of the pilot, despite issues with scanners and scanning applications, they were able to scan enough to demonstrate what 2023 might look like.

Most importantly, the pilot demonstrated that GS1 standards enable an efficient 2023 interoperable system. Not only does this include EPCIS 1.2 for exchange of Transaction Information and Transaction Statement, but also the use of a GS1 DataMatrix® and GTINs for product identification. Without the use of a standard that addresses product identification, information capture, and information sharing, effective implementation of 2023 requirements will be next to impossible.

SECTION 2: BACKGROUND

DSCSA "Serialization" Timeline

The following is an abbreviated timeline of requirements excerpted from the background section of the FDA document, "Product Identifier Requirements Under the Drug Supply Chain Security Act–Compliance Policy Guidance for Industry–Draft Guidance."

11/27/2017

- Manufacturers are required to "affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce." Drug product considered to be misbranded if it fails to have the product identifier.
- Manufacturers must use the standard numerical identifier, which is part of the product identifier, to verify product at the package level, when investigating suspect product or upon receiving a verification request from FDA or state agency.

11/27/2017 ➔ 11/26/2018 [enforcement discretion]

- FDA does not intend to take action against manufacturers who do not affix or imprint a product identifier to each package and homogenous case of products intended to be introduced in a transaction into commerce before November 26, 2018.

11/27/2018

- Re-packagers are required to engage only in transactions involving products that bear a product identifier.
- Re-packagers are required to "affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce" Drug product considered to be misbranded if it fails to have the product identifier.
- Re-packagers must use the standard numerical identifier, which is part of the product identifier, to verify product at the package level, when investigating suspect product or upon receiving a verification request from FDA.

11/27/2019

- Wholesale Distributors are required to engage only in transactions involving products that bear a product identifier.
- Wholesale Distributors are required to verify saleable returns against the original TI, TH, and TS.

11/27/2019 ➔ 11/27/2020 [enforcement discretion]

- Wholesale Distributors are required to verify the product identifier on each package or sealed homogenous case of such product that they intended to further distribute as a saleable return.

11/27/2020

- Dispensers are required to engage only in transactions involving products that bear a product identifier.
- Dispensers are required to verify product in certain circumstances at the package level, including the standardized numerical identifier

11/27/2023

- Manufacturers, Re-packagers, and Wholesale Drug Distributors must include the product identifier in the transaction information and have systems and processes necessary to retrieve previous transaction information.

DSCSA Stakeholders

Stakeholders in the end-to-end supply chain that will be impacted by DSCSA include manufacturers, re-packagers, third-party logistics providers (3PL), wholesale distributors, and dispensers.

Manufacturers: The participating manufacturers were representative of supply partners including small, midsize and large branded manufacturers, generic manufacturers, 3PLs and re-packagers.

Wholesale Distributor: AmerisourceBergen, is uniquely positioned as a private label manufacturer, re-packager, 3PL distributor and specialty pharmacy which enabled them to give firsthand perspective from every point in a vast and complex global supply chain.

Dispensers provided insight into receiving EPCIS into a third-party DSCSA solution and internal pharmacy operations software that is integrated with AmerisourceBergen's DSCSA/EPCIS system.

POC Pilot Participants

A list of the POC pilot participants is listed below which represents a realistic cross section of the end-to-end supply chain that will be impacted by the 2023 DSCSA requirements.

COMPANY	FACILITY LOCATION	PRIMARY CONTACT	TYPE OF ENTITY	COMPANY SIZE
AMAG/ ICS	Louisville, KY	Prakash Christopher	Virtual	51-200
AmerisourceBergen	Columbus, OH (FDC)	Matt Sample	Private Label Manufacturer, Re-packager, 3PL, Specialty Pharmacy	10,001 +
Amgen	Louisville, KY	Nikkhil Vinnakota	Branded	10,001 +
Apotex	Indianapolis, IN	Stephen Coady	Generic	10,001 +
Eli Lilly	Indianapolis, IN	Senthil Rajaratnam	Branded	10,001 +
EMD Serono	Louisville, KY	John Ryan	Branded	501-1000
Genentech	Louisville, KY	Vidya Rajaram, Kathy Daniusis	Branded	10,001 +
J&J	Memphis, TN	Becky Hehnly	Branded	10,001 +
Mylan	Charlotte, NC	Mark Gutman	Generic	10,001 +
Pfizer	Memphis, TN	Mike Mazur, Allison Sheldon	Branded	10,001 +
rfXcel	Reno, NV	Brian Bilyeu	Solution Provider	n/a
SAP	Waldorf, Germany	Oliver Nuernberg	Solution Provider	10,001 +
The Christ Hospital	Cincinnati, OH	Dave Fye Justin Gamble	Dispenser using AmerisourceBergen customer portal	5001-10,000
Tracelink	n/a	n/a	Solution Provider	n/a
Walgreens	Mansfield, OH	Bill Homa Melva Chavoya David Brown	Dispenser receiving EPCIS using rfXcel – 3rd party DSCSA solution	10,001 +

Dispenser Readiness

As outlined in the executive summary, a primary goal of the POC pilot was to determine operational impact of the 2023 requirements on the Dispensers. To understand the impact, it was important to understand Dispenser Readiness.

Xavier University graduate students of the College of Professional Sciences conducted interviews of multiple dispensers and provided findings as to the level of knowledge dispensers had of the requirements and to determine where they were in their plans to meet the upcoming requirements.

The key takeaways were that the dispensers' knowledge around 2023 requirements varied widely. Many dispensers plan to rely on their upstream supply chain partners to guide them through what is needed for 2023. While there were many dispensers who were eager to learn more about the impending requirements, there were fewer who were prepared or willing to join the POC pilot. The dispensers who were eager to join the pilot represent a cross section of varying supply chain scenarios regarding systems and technical partners who would be responsible for implementation.

The EMD Serono Pilot Team (Krishnaveni Myneni, John Ryan)

Manufacturer and Wholesaler Readiness

Since 2015, AmerisourceBergen has been working with manufacturers on conducting several DSCSA data exchange pilots. These pilots provided insight into what it was like to move serialized product, and the subsequent TI data, from a manufacturer through to a drug wholesaler. The following are links to the studies published:

2015 Piloting Traceability with GS1 Standards

https://www.gs1us.org/DesktopModules/Bring2mind/DMX/Download.aspx?Command=Core_Download&EntryId=718&language=en-US&PortalId=0&TabId=134

2017 Exceptions Pilot

https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/manufacturer/2018_exceptions_pilot_whitepaper.pdf?la=en&hash=BBF9FEE36546C99FE929EF3115D6C56660B4812A

Manufacturers were eager to participate in this end-to-end POC pilot, to gain an understanding of the downstream impact of the systems and processes already in place.

SECTION 3: PROOF OF CONCEPT (POC) PILOT DESCRIPTION

Goals and Objectives

The overall objective of this pilot was to further explore the opportunities and challenges associated with interoperable DSCSA data exchange between manufacturers and wholesalers, as well as to pilot similar technical solutions with dispensers. The two primary goals were to:

1. Demonstrate, with interoperable 2023 Transaction Information (TI), Transaction Statement (TS) exchange, enhanced unit level traceability from a manufacturer, to the wholesaler, and ultimately the end dispenser
2. Understand the dispensing communities' requirements, potential approaches and challenges with meeting the 2023 DSCSA statutory requirements.

Additionally, the stakeholder groups (manufacturers, wholesalers, dispensers) identified distinct goals during the planning of the pilot:

- Identify internal business process changes required to be able to receive the serialized product and confirm, with appropriate quality checks, the receipt of TI.
- Confirm the process of shipping and receiving serialized product, and identify additional challenges and opportunities.
- Understand the potential benefits of serialization (counterfeit prevention, inventory/order accuracy, analytics, recall management, etc...).
- Understand the differing technical requirements of dispensers and the costs associated with developing those capabilities.
- Identify and measure exceptions and challenges in implementing 2023 enhanced unit level traceability.
- Identify where technical, or data errors, may result in false concerns over suspect product.

The ultimate success criteria were defined as the ability of trading partners to qualitatively accomplish the above objectives and gather enough data to quantitatively identity exceptions, operating costs, and potential disruptions with implementing 2023 requirements.

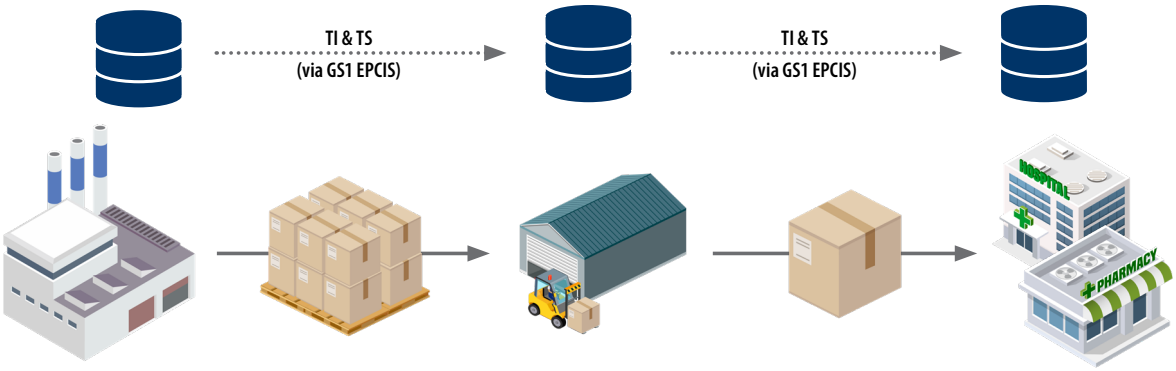
Systems, Process Flows, Region

On the next page is a high-level process flow that was followed (**Figure 1**). The POC pilot locations were chosen based on their location in the Central Region to optimize Project Managers oversight and technical capabilities.

In order to demonstrate the interoperable exchange of serialized data (TI, TS), using GS1 EPCIS, across distributed, de-centralized, systems, a unique solution was planned to be used by each of the dispensers.

Walgreens planned to receive EPCIS events from AmerisourceBergen directly into their 3rd party DSCSA solution through rfXcel, have aggregated data available at time of receiving, and then scan a sample of products at receipt to perform an audit. This pilot process (**Figure 2**) was to be performed in addition to their existing receiving process.

End-to-End Process Flow (High Level)



- Send serialized products to AmerisourceBergen
- Transmit serialized GS1 EPCIS files along with, or prior to, shipment

- Receive serialized products and GS1 EPCIS data; confirm receipt of TI, TS
- Scan and aggregate at outbound shipments
- Build customer capabilities for DSCSA: Send GS1 EPCIS, enhance customer portal, update customer handheld, etc.

- Receive serialized products and GS1 EPCIS data (TI, TS) and integrate to customer solution; or
- Receive serialized products and data (TI, TS) using ABC solutions

Figure 1

Walgreens POC Pilot Process

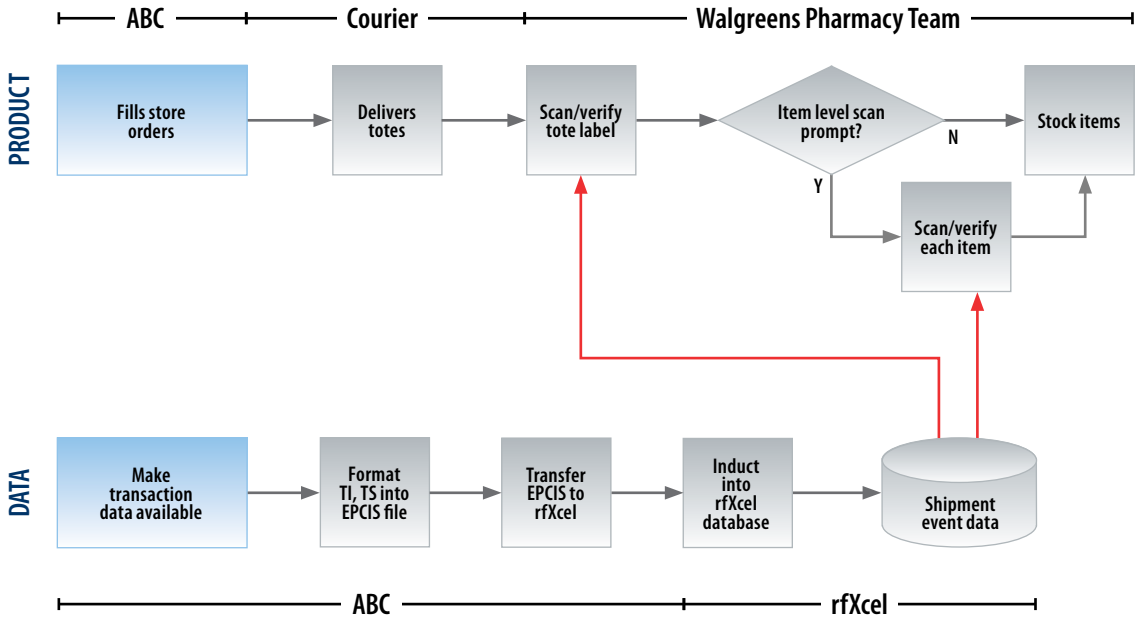


Figure 2

The Christ Hospital POC Pilot Team

The Christ Hospital used AmerisourceBergen's dispenser portal to integrate DSCSA TI, TS serialized data into their receiving processes and planned to scan each unit and case upon receipt (**Figure 3**).

In Scope Products

The products that were in scope for the pilot were determined based on the following criteria:

- Shipping/Receiving locations of dispensers' partners were within the Central Region for optimal oversight by Project Managers and technical capabilities.
- Products were shipped to the AmerisourceBergen Distribution Centers in Columbus, Ohio.
- Product was aggregated so that efficient EPCIS exchange was possible.
- No controlled substances were included in the pilot.

A complete list of products can be found in Appendix 1.

Evaluation Methods

Data was collected from systems and manual observation, where possible, to capture the metrics. Feedback from operators and employees was gathered to evaluate human factors and other qualified concerns. Each participating entity provided their own conclusions and identified opportunities which are summarized in the POC Pilot Results.

Given that there is no other globally recognized interoperable standard for exchanging serialized information, other than what this pilot utilized (GS1 EPCIS), the output is focused on the learnings, and recommendations on technology and process.

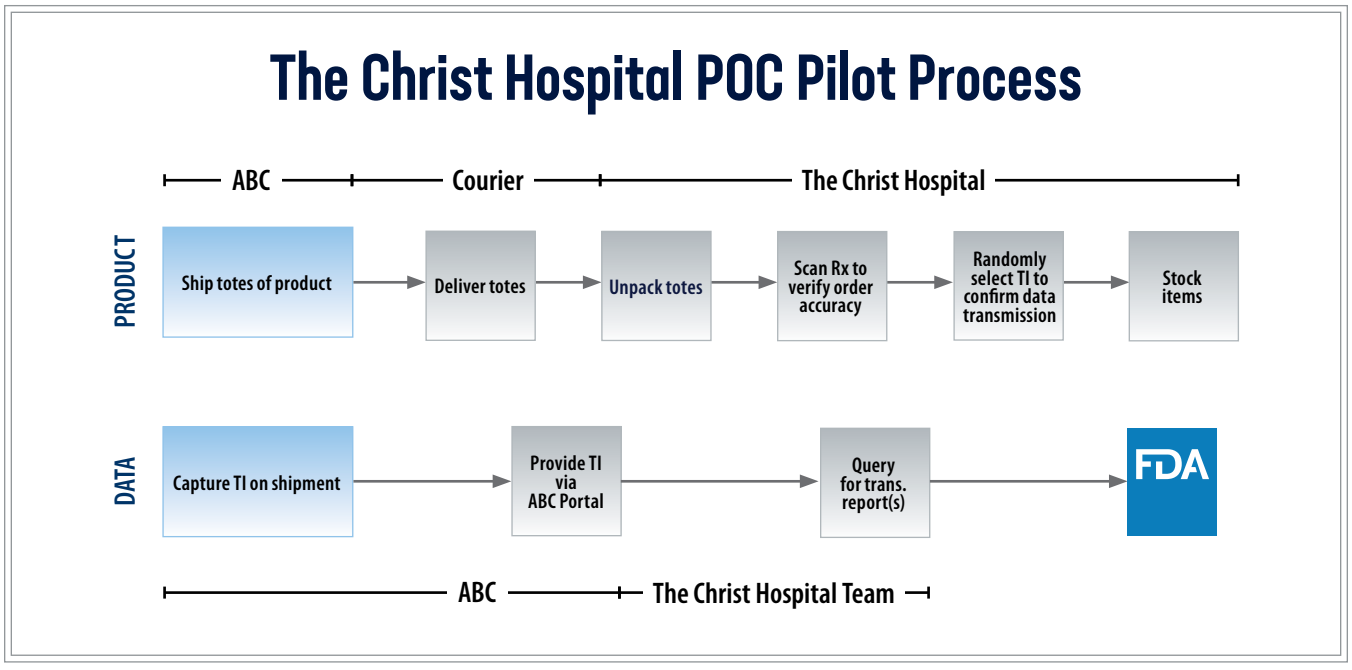


Figure 3

SECTION 4: POC PILOT RESULTS

Metrics and Measurements

Following is the data collected during the pilot. Manufacturers began shipping pilot products in advance to allow AmerisourceBergen to build as much inventory as possible that was in pilot scope. However, some of the shipments were received into the NDC and the products that were shipped from the NDC to the FDC were not scanned. This limited the pilot to only a few manufacturers and limited the overall number of shipments inbound that could be used for the pilot.

AmerisourceBergen scanned all outbound shipments for the pilot. However, there were a high volume of scanned units that were received prior to the beginning of pilot data exchange, and therefore had no TI.

At the receiving end, the dispensers experienced issues with both scanning applications and scanners. Walgreens experienced an issue with their scanning application that was resolved toward the end of the pilot. Once resolved, an additional three days was added to the pilot so they could scan received product. The Christ Hospital had issues with their scanner so used an existing linear scanner to receive product and manually verified product received versus TI/TS data received.

Manufacturer Outbound:

Due to order patterns and the controlled pilot, outbound shipments were limited to five manufacturers.

- Total Cases Shipped: 19,168
- Apotex: 17,283
- Amgen: 544
- Eli Lilly: 1,070
- EMD Serono: 240
- Pfizer: 31

AmerisourceBergen Inbound:

- Total Scans: 406 (174 Eaches; 232 Cases)
- Total Scans where TI Existed: 3 (product was received prior to TI)
- Total EPCIS Events: 558 Files
- Failed Files: 1 (Due to product being scanned prior to EPCIS event)
- 99.8% Performance Rating for EPCIS

AmerisourceBergen Outbound:

- Total Scans: 736 Scans (All Eaches)
- Total Scans where TI existed: 239
- 392 Total Shipments
- 232 Files Posted
- 200 Files Posted Correctly the first Submission
- 86% Performance Rating for Posted Files

Dispensers Inbound (Walgreens):

- Total Walgreens Scans over 3 days: 43
  - » 33 Items
  - » 10 Totes
- Total Files Uploaded by rfXcel: 3
- Total Files Posted Correctly the first Submission: 3
  - » Encountered (1) timing issue where EPCIS file was not loaded prior to store receiving shipment
- Performance Rating
  - » Totes: 100% (10 out of 10)
  - » Rx Items: 79% (26 out of 33)
    - – (1) incorrect upstream data caused serial # mismatch at store scan
    - – (6) issues seen with expiry date data sent did not match 2D barcode data

Challenges and Lessons Learned

With any new requirement, there will be challenges and those challenges will vary for each supply chain partner. The following 12 challenges were denoted as being significant obstacles for 2023 requirements.

1.) Current AmerisourceBergen DSCSA Solutions Will Not Be Able to Sell Product for Inventory Received Prior to November 27, 2023, Which is Missing Transaction Information (TI)

AmerisourceBergen built their IT solutions specifically not to send serialized TI data without the original enhanced (serialized) Transaction Information (TI) and Transaction Statement (TS) receipt from the manufacturer. Although they intend to check at receiving in November of 2023, to ensure the receipt of TI and TS, they also want to ensure every unit sold is compliant. However, there will certainly be product that has been received and in inventory prior to November 27, 2023, and those items may not have accompanied enhanced TI and TS. When AmerisourceBergen goes to ship these products, they will be blocked by the system in doing so due to missing TI.

Key Lesson Learned:

- Just as the industry learned with the 2017 Serialization grandfathering approach, it will be very challenging and possibly impossible to track what product was received prior to November 27, 2023. In order to not disrupt the supply chain, a phase-in period is required as the supply chain turns over old inventory, which may not have had enhanced TI. If a pragmatic approach is not allowed, it could result in significant supply issues.

2.) Lack of clear and timely guidance from the FDA on Standards.

Industry is seeking clear and timely guidance on the interoperable standard that is to be used for November 2023. The assumption is GS1 Identification, Barcodes and EPCIS will be used, as it's the only global standard for serialized transactions, however, without guidance embracing the use of GS1 standards, trading partners may look for alternative solutions. Furthermore, with GS1 EPCIS 1.2 specifically, there are many attributes that can be provided in addition to the minimal elements of the Transaction Information and Transaction Statement (i.e., purchase orders are not required to be part of transactions, but they are needed to be able to manage exceptions).

Key Lesson Learned:

- As trading partners move towards 2023 data exchange, it is critical that both the FDA provide guidelines where they have authority to do so, and the industry work on development of guidelines or best practices for EPCIS in the event that the FDA guidance's don't address the current ambiguity. Training is critical and the industry, along with GS1, need to continue to educate.

3.) System Integrations and Onboarding

There were technical issues exchanging data between AmerisourceBergen and Walgreens EPCIS systems due to AmerisourceBergen using a DSCSA solution in a production environment and Walgreens using a DSCSA solution in a test environment. AmerisourceBergen's solution provider had a policy that would not allow integration of production systems to non-production systems to facilitate the pilot. This led to issues in connecting systems to exchange EPCIS data. Walgreens was using a test system, whereas AmerisourceBergen was live in production. Based on this, EPCIS data had to be exchanged manually via email.

Key Lesson Learned:

- Although not expected to be an issue for November 27, 2023, as everyone should be on production instances, this is a consideration when thinking about trading partner testing and onboarding. AmerisourceBergen's experience

to date is that a well-documented process around testing and onboarding trading partners is required and that this process should be done in a stage, or quality environment. If trading partners plan to conduct tests, it is recommended that it be in a production environment, using production product as that is the only proven method to uncover issues related to the physical product barcode or volume.

4.) Product and Location Master Data Exchange and Accuracy

Many, if not all of the current EPCIS systems, require specific GS1 identifiers be loaded for product (Global Trade Item Number - GTIN) and locations (Global Location Number - GLN and Global Company Prefix - GCP), prior to receiving EPCIS files and transacting serialized product. During onboarding and testing to use EPCIS for the exchange of TI and TS, manufacturer's files were often found to have missing or incorrect GTIN, GLN, or GCP data. In addition, AmerisourceBergen's EPCIS solution required product Unit of Measure and Quantity attributes in addition to just the GTIN. Walgreen's solution required even more attribution unique to their system that AmerisourceBergen didn't require. The process of exchanging master data was manual, and painful at best, with multiple iterations of emails, testing, failures, and correction.

Key Lessons Learned:

- As we look at November 2023, there will be 500 manufacturers that must exchange new master data elements with approximately 200 distributors, and potentially 200,000 dispensers. There needs to be an agreed to method and attribute list that can be utilized in order to share this much data consistently from manufacturer to downstream trading partners. Also, solution providers need to take more pragmatic approaches to how they process serialized transactions. For example, AmerisourceBergen's EPCIS solution fails an entire EPCIS file if only one product is missing a GTIN in the system. Ideally, it would process those products that required master data exists, and manage to the exception.
- This might be an opportunity for the Pharmaceutical supply chain to leverage a system where industry is already sharing master data. Void of a non-manual solution, this may result in missing or incorrect master data being used throughout the supply chain and potential disruption of supply due to systemic constraints.

5.) Product Labeling and GS1 DataMatrix® Barcodes

During AmerisourceBergen's receiving and shipping processes, multiple issues were found where a barcode could not be scanned including: multiple 2D barcodes on a product with no clear indication of the DSCSA barcode; multiple barcodes too close together causing scanner or human error; barcodes that were too shiny creating a glare; barcodes using "00" day for expiration dating; and barcodes formatted incorrectly and not following GS1 standards. Some of these issues may result in slower processing of the product, while others may result in errors with shipping, or the inability to sell products to downstream trading partners.

Key Lessons Learned:

- The industry has been driving towards standardized product packaging, utilizing GS1 standards, since the passing of DSCSA and the mandated use of serialized product identifiers, in order to avoid operational issues or interrupted patient access; there is still

work to do. Similar to the request that FDA acknowledge GS1 standards for the exchange of enhanced Transaction Information, a similar acknowledgement of GS1 standards for the encoding of the product identifier in the required homogenous case and unit barcodes would assist standardizing compliance.

- Manufacturers must make sure they are aligning to the US GS1 DSCSA Implementation guidelines with regards to aligning on expiration dating in both the GS1 DataMatrix®, and EPCIS data. Using "00" to represent the day of the month, although historically acceptable, WILL cause data mismatches in 2023. Databases cannot process a "00" date. Of the total scans performed by AmerisourceBergen 20% of them had barcodes that encoded a "00" date. Although our systems are sophisticated to determine the actual end-of-month date, this will most certainly cause challenges at downstream dispensers and others with less intelligent systems.
- The industry needs to address both usability of barcodes (i.e., multiple barcodes too close together), and unreadable barcodes. If drug wholesale distributors and dispensers are unable to use the new DSCSA barcode due to too many barcodes too close, incorrect encoding, or "shiny" labels, it may prevent product from making it to the patient. This may create new exceptions that could lead to additional labeling related recalls as well. Over the next four years, it's important that manufacturers build in quality control processes during artwork creation and product packaging to ensure that each homogenous case labeling is compliant to GS1 standards, readable with a non-vision inspection system, and of high enough quality that lower cost dispenser scanners can read them.

6.) Building New Apps for Existing Equipment

Some dispensers are dependent on their solution providers to build, configure and format their hardware/software solutions; scanning new GS1 DataMatrix® barcodes for DSCSA is technically more complicated than the historical linear barcodes. rfXcel developed a mobile application for Walgreens, to verify serialized prescription products upon receiving at an Ohio pharmacy. Very close collaboration was needed to assure the native scanning application was compatible with the versions of the operating system and development tools of the Zebra scanner. Once addressed, the pharmacy team was able to scan inbound products and verify product identifier data.

Key Lessons learned:

- It is important to do a 100% audit of hardware and software to be sure all are compliant. If trading partners have multiple locations, assumptions should not be made that they all are using the same hardware and software.
- Not all patches/software upgrades are "plug and play" and supply chain partners may require technical assistance and additional support to install new versions of mobile apps and scanner upgrades.

7.) Human Factors Impact and potential Supply Chain Efficiencies

There are multiple human factors issues related to scanning barcodes that will have a significant operational impact in 2023. These issues include:

- Scanning the wrong barcode due to multiple 2D barcodes on a product and no clear indication of which to scan (i.e., scattered human readable information)
- Scanning the wrong barcode due to barcodes being too close to each other or too many on the same scan panel.
- Knowing the proper technique to scan a 2D barcode compared to the historical linear barcodes.
- Manual entry of product identifier information leads to significant errors (0 vs. O, 1 vs. l, etc.).

Key Lessons Learned:

- There will be a learning curve for operators both in 2023 implementation and ongoing through employee turnover. The more manufactures can minimize multiple barcodes on the same panel and include the human readable product identifier next to the 2D barcode that is scanned, the easier the learning curve will be.
- It is not advised to utilize the human readable information when transacting product, specifically the serial number and lot number, as typos and transcription errors occur that may lead to data mismatch and potential patient-care impact.

8.) Observed Issues with EPCIS Exchange

There were several instances where files were not formatted correctly, or they did not process correctly during the staging and onboarding process and may create issues as the industry deploys this relatively new data transmission standard:

- Warehouse process errors resulted in the quantity of product identifiers in the EPCIS not equaling the quantity of products shipped and received. Without proper exception handling and reporting these errors might not be caught until the product is sold to subsequent trading partners.
- As observed during this pilot, and past pilots, the product appears prior to the transaction information which will result in future supply disruptions.
- EPCIS data files were too big to process.
- Manufacturer's expressed that EPCIS can be very large due to the number of items that are on one PO from various customers. Some file sizes seen have been more than 34MB. Supply chain partners may not be aware of the amount of data or time/power needed to process this amount of data.
- Required Transaction Information was missing from the file, although the file was successfully transmitted.
- GTIN, GLN, and GCP master data attributes were incorrectly formatted in the EPCIS file causing the processing to fail.
- GTIN, GLN, and GCP master data was missing from the downstream processing system causing the entire EPCIS file to fail.
- Transition from previous version of EPCIS (1.1 to 1.2) caused issues with how master data was mapped causing formatting errors.
- Issues with sequencing events in serialization systems occurred because packing events were posted at a later timeframe than shipping events. This occurred when daylight saving time came into effect in different time zones. This led to discrepancies in outbound messages being sent to wholesaler without packing events.
- Some Level 4/Level 5 enterprise systems do not accept GS1 US Healthchare standard EPCIS, they rely on custom extensions to operate. This makes it difficult to operate due to differing partner setups.
- Some partners do not have a good technical knowledge/support for EPCIS and transfers, which can make it more difficult to work with them.
- Some partners do not check their systems for failed documents, they simply tell their partner that the document was not sent.
- System processing and transmission times must take into consideration the availability of data at dispenser locations prior to product delivery. Serialized data must be generated at the distributor, transferred, successfully accepted to dispensers' systems, and loaded into repositories by the time the courier makes the first delivery at the pharmacy. Failure to do so will impact the receiving process and possibly delay the ability to provide patient care.

Key Lessons Learned:

- Master data issues will continue to be challenging.

- Need fail-safes in place to ensure data integrity, and that files are sent in the right format.
- Need to ensure sufficient impact assessment of any changes in EPCIS versions and formatting for future compatibility.
- Interoperable data exchange using GS1 EPCIS, will be a heavy lift for the industry come November 2023 and implementations should start at least a year out. Issues will occur and can take months to overcome.
- Systems must be optimized assuring efficient processing, transmission, loading, and exposure of the serialized data at dispensing locations.

9.) Dispenser Training

In multiple cases, dispensers are relying heavily on their upstream partners to provide training and guidance or they are investing their own resources to adhere to the guidance. AmerisourceBergen has an entire training team dedicated on how to use their application at The Christ Hospital. AmerisourceBergen has over 50,000 customer locations and there is a concern that the sheer volume of dispensers seeking training will not be sustainable for upstream partners.

Key Lessons Learned:

- Dispensers will need new or modified processes. While developing these new processes and selecting hardware to facilitate these processes, care should be taken to consider the impact to dispensers' ability to quickly receive and verify product in order to avoid delays in providing patient care
- For those trading partners who provide solutions to their downstream trading partners, resourcing and planning will be critical to ensure the proper level of training is delivered before the November 27, 2023.

10.) Aggregation Enables the Efficient Exchange of Enhanced TI

As experienced by both the participating manufacturers and AmerisourceBergen, inference, and the enabling aggregation, is necessary to ensure the efficient flow of serialized product to move from manufacturer, to AmerisourceBergen, and to the dispenser. Aggregation, both during product packaging, and to mixed totes/logistic containers during distribution, allows trading partners to generate enhanced TI without scanning each and every unit within a homogenous case when selling cases. It also enables trading partners receiving serialized product to utilize inference to check and confirm the receipt of TI.

Key Lesson Learned:

- Void of inference, and the enabling aggregation, would have resulted in AmerisourceBergen scanning tens of thousands of units at receipt of product during this pilot vs. the 406 units scanned. Likewise, Walgreens would have had to scan 43 individual units vs. 10 totes based on a small order sample of select manufacturers over 3 days in only one of nearly 9300 stores. Although not explicitly required by DSCSA, inference, and its enabled aggregation, is required to move serialized product as efficiently as possible come November 27, 2023.

11.) No Current Way for Industry to Share and Align on Status of a Single Serial Number

In order to avoid replication issues with serial number status, there must be a clear way for any authorized trading partner to update and share. For example, if a serial number is stolen from any supply chain partner, the last owner should be able to quickly update the status in a way that would allow any dispenser to know immediately that it has been stolen. This must be possible whether it happens at a manufacturer, distributor or dispenser and consider if the stolen product shows up at any other party.

Key Lessons Learned:

- The industry and the FDA must align on a forum and process to outline how such system should work.

- Approach must take into consideration input from all sectors of the supply chain.

12.) Solution Providers' Interpretation of the GS1 EPCIS Standard Could Translate into Different System Implementations

This manifested itself where one solution provider did not permit an alpha numeric GLN extension, although it was in fact permitted in the GS1 EPCIS standards. Additionally, there were other instances where some solution providers represented GLNs in the SGLN format vs. GLN format.

13.) Ordering Processes are Complex, Adding to the Need to Have a Robust TI Transfer

Dispensers order products in individual units, packages, partial packages or cases. TI transfer would need to accommodate for this complexity as well as for returns and credits. Often, a return or credit is a result of the dispenser inadvertently over-ordering, incorrectly selecting an item, damaged goods, aggregation issues, etc. zA return could occur months after a product has been shipped.

Summary of Findings

Start looking at 2023 now. 2023 is only three years away and considering what the ultimate 2023 interoperable system will be, there are numerous unknowns. Trading partners should not wait to get engaged. Although other technologies may emerge to compliment the exchange of data, the pilot participants believe that EPCIS will be used to exchange the Transaction Information and Transaction Statement in 2023.

Manufacturers should ensure their labeling and barcodes align with GS1 standards. In addition, they should begin making sure they, or their third party logistics partners, will have the hardware and software capabilities to capture and generate DSCSA compliant EPCIS messaging.

Drug Wholesalers should make sure their scanning technology can read the new 2D DataMatrix® barcodes and that they can also capture, aggregate, and generate EPCIS messages upon sale to their customers.

Dispensers should begin evaluating how they intend to be compliant to 2023 DSCSA requirements. This is a time-consuming process. Some considerations include:

- Will they scan every unit?
- Will they manually audit shipments?
- How will they verify they have received the Transaction Information and Transaction Statement if they intend to scan each unit?

They will also need to understand the impact to their current hardware and software landscape by considering how many devices are in the field, if all the devices are the same, if all same devices are on the same version, or if all devices need to be updated. Finally, if dispensers rely on their wholesale drug distributor for DSCSA software and compliance, they should engage on requirements and testing sooner than later.

Supply chain partners should also look to mechanisms to stay engaged, whether it be industry advocacy groups, the newly formed governance body, or one-on-one with trading partners. With so much to do between now and November 2023, it is imperative that industry work together to ensure business is not interrupted and patients receive the products they need.

Understand and Plan for Incremental Operating Costs Associated with Implementing 2023 Enhanced Unit Level Tracking

Based on sensitivity of sharing specific data regarding expenditures and the variability across all business models, hard costs were not calculated. However, the following are costs that are associated with operating in a 2023

environment and will have a significant impact on all supply chain partners:

1. Capitol hardware and software development and/or upgrades
2. Scanning – the time to scan has a significant business and operational impact particularly if there are scan errors. Of most significance is scanning every unit in high volume/automated instances (i.e., wholesalers, distributors)
3. Onboarding and maintaining interoperable connections and data management
4. Training and change of management

Plan on More Piloting

The pilot team accomplished a great deal in the weeks we executed the effort, however, there is still more industry needs to understand. Although a significant number of products were scanned compared to past pilots, the pilot didn't transact anywhere near the typical three million AmerisourceBergen daily transactions.

To truly understand the impact of 2023, including the technical performances of systems and the EPCIS messaging standard, we need to run in full 2023 mode with all products. Until that occurs, we won't fully understand the operational impact, number of exceptions to expect, or most importantly, the design processes to prevent data errors from impacting patient access.

Finally, this pilot merely scratched the surface of the dispenser role in 2023 requirements. We were successful in proving concept, however, much more testing and piloting is needed for dispensers to understand the business implications, develop solutions, train their inbound operators and implement receiving processes.

Treat This as Transformational

DSCSA should not be treated as a one-off initiative, program or project. It is not as simple as putting a new barcode on products, or new technology solutions in place. Perhaps more importantly, it is not just a packaging or IT effort; it is a business transformational program.

Opportunities Identified

While the challenges may seem overwhelming, the pilot provided the opportunity for each entity to analyze their current systems, processes and in some cases equipment. Several identified areas for improvement in order fulfillment, training, process updates, and exceptions handling. Identifying these opportunities early, positions us to put new and improved processes in place for future pilots and ultimately 2023 implementation. Integrating systems across the supply chain is no small feat, however, opportunities revealed themselves to put fail safes in place for connections, ensure links are created for new partners and implement necessary EPCIS testing scenarios for successful data exchange.

SECTION 5: NEXT STEPS FOR AMERISOURCEBERGEN, AND ITS TRADING PARTNERS

As learned from past pilots, the more time you execute the pilot, the more learnings you have. Given the complexity of this pilot and the number of trading partners, four to five weeks was not enough. AmerisourceBergen plans to operate its large, automated, Columbus DC in full 2023 mode for six to 12 months starting in mid-2020 to both better measure internal operational impacts as well as to allow its upstream and downstream trading partners to pilot ad-hoc with them.

AmerisourceBergen plans a full warehouse and product audit for barcode compliance to GS1 and readability. Dispensers are starting to scan 2D barcodes and expect all manufacturers to be compliant to GS1. Without GS1 barcode compliance, dispensers won't be able to utilize the 2D code prior to 2023 for further piloting, and will be at risk for 2023 deadlines.

In conclusion, AmerisourceBergen, and trading partners in this pilot, plan to be leaders in emerging technology and will offer input as requested in governance discussions. The use of GS1 EPCIS 1.2 for exchange of TI and TS will surely be part of 2023, however, other technologies may augment the exchange of data. As leaders, the pilot participants have an interest in being involved to see how new technology and processes will be governed, if at all. Anything beyond data exchange between trading partners complicates the security of "authorized trading partner" and the consistent application of technology and standards. While there are still questions left unanswered, leaders have emerged who are motivated to work with their trading partners, the industry, GS1 and the FDA to ensure a true interoperable system is ready for 2023 and most importantly, patients continue to have access to the safe medications they need.

ABOUT THE PILOT CO-LEADERS

AmerisourceBergen commissioned Xavier Health to do an in depth study of the POC. Xavier Health is a community of hundreds of FDA, industry experts, thought leaders and academics. Xavier Health was formed in 2008 as an outreach of Xavier University and is charged with making a difference in the pharmaceutical, medical device, and combination products industries.

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AmerisourceBergen, VP, Manufacturer Operations

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AmerisourceBergen, Secure Supply Chain Program Manager

Michelle Rich
Associate Director of Program Development, Xavier Health, Xavier University

Eric Arenas and Matt Sample at Xavier University

APPENDIX 1: POC PILOT PRODUCTS

MFG	NDC	DESCRIPTION	INBOUND (MFG→ABC)	OUTBOUND (ABC→DISP)
AMGEN	58406044504	Enbrel 50MG, 0.98 mL AI, 4pk		
AMGEN	58406043504	Enbrel 50MG, 0.98 mL PFS, 4pk	1	
APOTEX	60505082901	FLUTICASONE N/SPRY50MCG/MTRDOSE 15ML USA	1	1
APOTEX	60505025203	TIZANIDINE 4 MG	1	1
APOTEX	60505083305	AZELASTINE 137 MCG	1	1
APOTEX	60505082901	FLUTICASONE 50 MCG	1	1
APOTEX	60505009600	DOXAZOSIN 8 MG	1	1
APOTEX	60505017009	PRAVASTATIN 40 MG	1	1
APOTEX	60505001406	DILT-XR 120 MG	1	1
APOTEX	60505257909	ATORVASTATIN 20 MG	1	1
APOTEX	60505258009	ATORVASTATIN 40 MG	1	1
APOTEX	60505267109	ATORVASTATIN 80 MG	1	1
APOTEX	60505311100	OLANZAPINE 5 MG	1	1
APOTEX	60505311300	OLANZAPINE 10 MG UD	1	1
APOTEX	60505311400	OLANZAPINE 20 MG	1	1
APOTEX	60505252703	MODAFINIL 200 MG	1	1
APOTEX	60505084805	AZELASTINE 0.15 % NAS	1	1
APOTEX	60505615005	CEFTRIAXONE 10GM XL	1	1
BIONPHARMA INC.	69452020720	CALCITRIOL 0.25 MCG 100 CAP		1
ELI LILLY	2751017	HUMALOG	1	
ELI LILLY	2879959	HUMALOG KWIK PEN	1	
ELI LILLY	2771559	BASAGLAR 100 IU	1	1
ELI LILLY	2751001	HUMALOG 100 UN/ML	1	
EMD SERONO	44087002203	Rebif Syringe 22 mcg (12)	1	
EMD SERONO	44087004403	Rebif Syringe 44 mcg (12)	1	
EMD SERONO	44087100502	Saizen Vial 5 mg (1)	1	
EMD SERONO	44087332201	Rebif Rebidose 22 mcg (12)	1	
EMD SERONO	44087334401	Rebif Rebidose 44 mcg (12)	1	
EMD SERONO	44087018801	Rebif Rebidose Titration Pack 8.8 mcg (6 x 8.8 mcg + 6 x 22 mcg)	1	
GENENTECH	4082205	TAMIFLU DRY SYRUP 30 MG/5 ML 65 ML US	1	
GENENTECH	50242013601	ACTEMRA VIALS 200 MG/10 ML INTRAVENOUS 1 EA US	1	
GENENTECH	50242013701	ACTEMRA VIALS 400 MG/20 ML INTRAVENOUS 1 EA US	1	

MFG	NDC	DESCRIPTION	INBOUND (MFG→ABC)	OUTBOUND (ABC→DISP)
GENENTECH	50242013501	ACTEMRA VIALS 80 MG/4 ML INTRAVENOUS 1 EA US	1	
GENENTECH	50242008527	ACTIVASE LYOPHILIZED VIALS 100 MG-1-US	1	
GENENTECH	50242006001	AVASTIN VIALS 100 MG/4 ML 1 US	1	
GENENTECH	50242006101	AVASTIN VIALS 400 MG/16 ML 1 US	1	
GENENTECH	50242004164	CATHFLO ACTIVASE LYOPHILIZED VIALS 2 MG 1 US	1	
GENENTECH	50242092201	HEMLIBRA VIALS 105MG/0.7ML SUBCUTANE 1 EA US	1	
GENENTECH	50242092301	HEMLIBRA VIALS 150MG/1ML SUBCUTANE 1 EA US	1	
GENENTECH	50242092001	HEMLIBRA VIALS 30MG/1ML SUBCUTANE 1 EA US	1	
GENENTECH	50242092101	HEMLIBRA VIALS 60MG/0.4ML SUBCUTANE 1 EA US	1	
GENENTECH	50242013201	HERCEPTIN LYOPHILIZED VIALS 150 MG INTRAVENOUS 1 EA US	1	
GENENTECH	50242013468	HERCEPTIN LYOPHILIZED VIALS 440 MG-1-US	1	
GENENTECH	50242015001	OCREVUS VIALS 300 MG/10 ML 1 EA US	1	
GENENTECH	50242014501	PERJETA VIALS 420 MG/14 ML 1 EA US	1	
GENENTECH	50242010040	PULMOZYME AMPOULES 2.5 MG/2.5 ML 30 US	1	
GENENTECH	50242005121	RITUXAN VIALS 100 MG/10 ML INTRAVENOUS 1 EA US	1	
GENENTECH	50242005306	RITUXAN VIALS 500 MG/50 ML INTRAVENOUS 1 EA US	1	
GENENTECH	4082205	TAMIFLU DRY SYRUP 30 MG/5 ML 65 ML US	1	
GENENTECH	50242012001	TNKASE LYOPHILIZED VIALS 50 MG 1 EA US	1	
GENENTECH	50242004062	XOLAIR LYOPHILIZED VIALS 150 MG 1 US	1	
GENENTECH	4025901	CELLCEPT 250 MG		1
GENENTECH	50242004164	CATHFLO ACTIV 2 MG		1
GENENTECH	50242008527	ACTIVASE 100 MG		1
GENENTECH	4110020	XELODA 150 MG		1
GENENTECH	4026129	CELLCEPT 200 MG/ML		1
GENENTECH	50242012001	TNKASE		1
GREENSTONE LIMITED	59762453802	MEDROXYPRO AC 150 MG/ML		1
GREENSTONE LIMITED	59762040101	SUCRALAFATE 1 GM 100 TAB		1
GREENSTONE LIMITED	59762033002	LATANOPROS WS 0.0000 2.5ML O/S		1
GREENSTONE, LLC (PFIZER)	59762-0531-1	PHENYTOIN 125MG/5ML ORSUS 8FLOZ BTL GRST	1	

MFG	NDC	DESCRIPTION	INBOUND (MFG→ABC)	OUTBOUND (ABC→DISP)
GREENSTONE, LLC (PFIZER)	59762-2350-5	ZARONTIN 250MG/5ML ORSOL 1X474ML BTL US	1	
GREENSTONE, LLC (PFIZER)	59762-0260-1	COLESTIPOL Hydrochloride - 30X5G (Unflavored Granules)	1	
GREENSTONE, LLC (PFIZER)	59762-0260-2	COLESTIPOL HCL 5G GOS 90X5G SCHT GRST	1	
GREENSTONE, LLC (PFIZER)	59762-0131-0	SILVER SULFADIAZINE 1% TCR 20G TUBE GRST	1	
GREENSTONE, LLC (PFIZER)	59762-0131-2	SILVER SULFADIAZINE 1% TCR 25G TUBE GRST	1	
GREENSTONE, LLC (PFIZER)	59762-0131-5	SILVER SULFADIAZINE 1% TCR 50G TUBE GRST	1	
GREENSTONE, LLC (PFIZER)	59762-0131-8	SILVER SULFADIAZINE 1% TCR 85G TUBE GRST	1	
GREENSTONE, LLC (PFIZER)	59762-0131-6	SILVER SULFADIAZINE 1% TCR 50G PJAR GRST	1	
GREENSTONE, LLC (PFIZER)	59762-0131-4	SILVER SULFADIAZINE 1% TCR 400G JAR GRST	1	
GREENSTONE, LLC (PFIZER)	59762-0067-1	SERTRALINE HCL 20MG/ML OS 1X60ML BTL US	1	
GREENSTONE, LLC (PFIZER)	59762-3728-1	CLINDAMYCIN PHOSPHATE (TOPICAL SOLUTION) 1%	1	
GREENSTONE, LLC (PFIZER)	59762-3728-2	CLINDAMYCIN PHOSPHATE (TOPICAL SOLUTION), USP 1%	1	
GREENSTONE, LLC (PFIZER)	59762-4940-1	SERTRALINE HYDROCHLORIDE (ORAL CONCENTRATE) 20 MG PER ML	1	
GREENSTONE, LLC (PFIZER)	59762-5025-1	GABAPENTIN 250MG/5ML ORSOL 1X5ML BTL US	1	
J n J	57894015512	ABIRATERONE ACT 250MG TAB 120	1	
J n J	59676096601	DOXORUBICIN 2MG/ML 1X10ML VIAL USA	1	
J n J	59676096602	DOXORUBICIN 2MG/ML 1X25ML VIAL USA	1	
J n J	10147089203	GALANTAMINE HBR ER CAP 16MG 30S 24 COUNT	1	
J n J	10147089103	GALANTAMINE HBR ER CAP 8MG 30S 24 COUNT	1	
J n J	10147089303	GALANTAMINE HBR ER, 24MG CAPSULES	1	
J n J	10147091101	HALOPERIDOL 5MG/ML 10X1ML AMP. USA	1	
J n J	10147092205	HALOPERIDOL DEC 100MG/ML 5X1ML AMP. USA	1	
J n J	10147092103	HALOPERIDOL DEC 50MG/ML 3X1ML AMP. USA	1	
J n J	10147015001	ITRACONAZOLE 1% 1X150ML ORSOL PATR-US	1	
J n J	10147170007	ITRACONAZOLE 100MG CAP 4x7x1 24C PATRIOT	1	

MFG	NDC	DESCRIPTION	INBOUND (MFG→ABC)	OUTBOUND (ABC→DISP)
J n J	10147170003	ITRACONAZOLE 100MG CAPSULES30X24 PATRIOT	1	
J n J	10147075005	KETOCONAZOLE 2% 1X120ML SHAMP USA	1	
J n J	10147068501	METHYLPHENIDATE ER TAB 18MG 100S 24 CTN	1	
J n J	10147068801	METHYLPHENIDATE ER TAB 27MG 100S 24 CTN	1	
J n J	10147068601	METHYLPHENIDATE ER TAB 36MG 100S 24 CTN	1	
J n J	10147068701	METHYLPHENIDATE ER TAB 54MG 100S 24 CTN	1	
J n J	10148201900	Miglustat Hard Capsules 100mg 90 caps US BL 15 Caps	1	
J n J	10147095103	PALIPERIDONE TAB,1.5MG,30S,12 CNT	1	
J n J	10147095203	PALIPERIDONE TAB,3MG,30S,12CNT	1	
J n J	10147095201	PALIPERIDONE TAB,3MG,HUD (2X5) X10,10CNT	1	
J n J	10147095303	PALIPERIDONE TAB,6MG,30S,12CNT	1	
J n J	10147095301	PALIPERIDONE TAB,6MG,HUD (2X5) X10,10CNT	1	
J n J	10147095403	PALIPERIDONE TAB,9MG,30S,12CNT	1	
J n J	10147095401	PALIPERIDONE TAB,9MG,HUD (2X5) X10,10CNT	1	
J n J	50458059601	RISPERIDONE 1 MG/ML 1X30ML SOLUT. USA	1	
J-O-M PHARM SERVICES	50458057930	XARELTO 20 MG		1
LILLY ELI & CO	2840001	FORTEO PEN 20 MCG		1
LILLY ELI & CO	2751017	HUMALOG		1
LILLY ELI & CO	66733095823	ERBITUX 200 MG		1
LILLY ELI & CO	2879959	HUMALOG KWIK PEN		1
LILLY ELI & CO	2879759	HUMALOG KWIK MIX 75/25		1
LILLY ELI & CO	2751001	HUMALOG 100 UN/ML		1
LILLY ELI & CO	2771227	HUMALOG KWIK PEN 200 UN		1
MYLAN	378827055	Albuterol Sulfate 0.083% 2.5mg/3mL 30x1	1	
MYLAN	378827052	Albuterol Sulfate 0.083% 3mL IS 5x5	1	
MYLAN	378699152	Albuterol Sulfate 0.63mg/3 mL 5x5	1	
MYLAN	51525047009	Cromolyn Sodium 100mg/5mL Amp 96s	1	
MYLAN	67457031625	Decitabine SDV 50mg	1	
MYLAN	67457058508	Fondaparinux Sodium 10mg/0.8mL PFS 10PK	1	

MFG	NDC	DESCRIPTION	INBOUND (MFG→ABC)	OUTBOUND (ABC→DISP)
MYLAN	67457058210	Fondaparinux Sodium 2.5mg/0.5mL PFS 10PK	1	
MYLAN	378967130	IpratropBr/AlbutSulf 0.5/3.0mg IS 1x30	1	
MYLAN	378718705	Metformin HCl BB 1000mg T 500s	1	
MYLAN INSTITUTIONAL./ PGN	51079086320	CAPTOPRIL 12.5 MG UD		1
MYLAN INSTITUTIONAL./ PGN	51079062383	SULFAMYLON 8.5 %		1
MYLAN INSTITUTIONAL./ PGN	51079002820	TACROLIMUS 5 MG UD		1
MYLAN INSTITUTIONAL/ GEN	67457045220	CYTARABINE 2 GM		1
MYLAN INSTITUTIONAL/ GEN	67457038499	HEPARIN SOD 1000 UN-ML 25X30ML MDV		1
MYLAN INSTITUTIONAL/ GEN	67457038599	HEPARIN SOD 1000 UN-ML 25X30ML MDV		1
MYLAN INSTITUTIONAL/ GEN	67457031625	DECITABINE 50 MG SDV		1
MYLAN INSTITUTIONAL/ GEN	67457053035	LEUCOVORIN 350 MG SDV		1
MYLAN INSTITUTIONAL/ GEN	67457090210	ETOMIDATE 20 MG 10X10ML		1
MYLAN INSTITUTIONAL/ GEN	67457090320	ETOMIDATE 40 MG 10X10ML		1
MYLAN PHARM	378699152	ALBUTEROL INH 0.63 MG		1
MYLAN PHARM	378247401	DICLOFEN POT 50 MG		1
MYLAN PHARM	378003210	METOPROLOL 50 MG PNK		1
MYLAN PHARM	378718505	METFORMIN 500 MG		1
MYLAN PHARM	378718705	METFORMIN 1000 MG		1
PAR PHARMA	63481052910	CORTISPORIN 10ML		1
PATRIOT PHARMACEUTICALS	10147089203	GALANTAMINE 16 MG ER		1
PFIZER PHARM	69046956	CHANTIX 1 MG		1
PFIZER PHARM	9003932	SOLU MEDRL N+ 40 MG		1
PFIZER PHARM	9004726	SOLU MEDRL N+ 125 MG		1
PFIZER PHARM	71036924	DILANTIN 100 MG		1
PFIZER PHARM	9082501	SOLU CORTEF 100 MG		1
PFIZER PHARM	49392083	GEODON INJ SDV 20MG		1
PFIZER PHARM	69047103	CHANTIX STRT MTH PK		1
PFIZER PHARM	69046903	CHANTIX 1 MG		1

MFG	NDC	DESCRIPTION	INBOUND (MFG→ABC)	OUTBOUND (ABC→DISP)
PFIZER PHARM	55724021121	EUCRISTA 2% 60GM ONT		1
SERONO LABS, INC.	44087100502	SAIZEN 5 MG		1
WOODWARD PHARMA	69784050001	NAPROXEN 500 MG DR 100 TAB		1

APPENDIX 2: DEFINITIONS, ACRONYMS AND ABBREVIATIONS

ABDC

AmerisourceBergen Drug Company: Serves Institutional healthcare providers, and retail pharmacies, providing pharmaceuticals, staffing, pharmacy automation and professional consultation services; delivers medicines purchased directly from the manufacturer to thousands of customers on a just-in-time basis.

ABSG

AmerisourceBergen Specialty Group

DQSA

Drug Quality and Security Act: US Federal law signed into law by President Obama on November 27, 2013, that outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.

DSCSA

The Drug Quality and Security Act (DQSA), was signed into law by President Obama on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act1, outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.

EPCIS

EPCIS is a GS1 standard that enables trading partners to share information about the physical movement and status of products as they travel throughout the supply chain – from business to business and ultimately to consumers

FDA

Food and Drug Administration: A government agency established in 1906 with the passage of the Federal Food and Drugs Act. With the passage of DSCSA the FDA now has expanded regulatory authority of wholesalers and dispensaries.

FDC

Forward Distribution Center – this is the distribution center that handles the forward distribution to all of customers. Forward DCs can receive products from the NDC (ABDC) as well as directly from manufacturers.

GLN

The Global Location Number (GLN) is part of the GS1 systems of standards. It is a simple tool used to identify a location and can identify locations uniquely where required. The GS1 Identification Key is used to identify physical locations or legal entities.

GS1

GS1 is a neutral, not-for-profit, international organization that develops and maintains standards for supply and demand chains across multiple industry sectors.

GS1 2D Data Matrix

GS1 DataMatrix is a two-dimensional (2D) barcode that holds large amounts of data in a relatively small space.

GS1-128

GS1-128 is an application standard of the GS1 implementation using the Code 128 barcode specification. The former correct name was UCC/EAN-128

GTIN

Global Trade Item Number (GTIN) is an identifier for trade items developed by GS1. For the purposes of serialization the industry will be using a 14 digit GTIN which contains he encoded 10 digit NDC.

Homogeneous Case

A packaging container, often called a case or shipper, that contains all of the same NDC or product.

Intercompany Shipments

Shipments that move between AmerisourceBergen facilities, specifically form the national distribution center to forward DCs as well as sales between ABDC and ABSG.

Interoperable Electronic System

Having transactions from one or more systems understood by another.

NDC

National Distribution Center—model in which manufacturer sends product to a central point for a majority of drug company purchases and they then are routed to the forward DCs for distribution to the dispensing customers.

Non-Homogeneous Case

A packaging container that contains mixed products or sometimes used in the event of a partial case of homogeneous products.

Product Case Label

This is the label that is applied to homogeneous cases. This typically contains the GTIN, Quantity, Lot, Expire, and quantity encoded in both linear and 2D DataMatrix barcodes.

Product Identifier

A standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that contains the standardized numerical identifier, lot number, and expiration date of the product.

Saleable Returns

Returned products intended for further distribution. Typically includes pharmaceutical product ordered in error or that is no longer needed by a pharmacy due to changes by the patient; salable returned product must include certification that the product has been stored under manufacturer's requirements

Serial Number Match

We have the serial number record in our internal enterprise system *and* it is OK to take an action against it. Matching occurs using the GTIN, Serial (sGTIN) during receipt and pick/pack/ship. At Returns, the match includes sGTIN, Lot, AND Expiration Date

sGTIN

For the US market, sGTIN is a serialized GTIN. When referring to a serial number, it is in fact always referring to the GTIN + SN combination. A Serial Number by itself is not unique until combined with a GTIN. Example: (01)0030456219999(21)1003451 is a valid Serial Number, (21)1003451 is not because it is not with an associated GTIN.

Shipper Label

This is a label that is applied to non-homogeneous cases, or customer containers, and Pallets. This label often contains logistics information and the SSCC(18).

SSCC(18)

The serial shipping container code (SSCC) is an 18-digit number used to identify logistics units. In order to automate the reading process, the SSCC is often encoded in a barcode, generally GS1-128.

Standard Serialized Numerical Identifier (SNI)

The term standardized numerical identifier refers to a set of numbers or characters used to uniquely identify each package or homogenous case. The SNI is composed of the National Drug Code (in GTIN format) that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

Customer Container

The lowest level container that is delivered to the customer or used for an internal transfer order. These may be cardboard boxes, or plastic totes. These may also be aggregated to high level logistic containers such as pallets or air freight containers.

Tote

Container that is used to store drug product during the picking processes.

Product Verification (DSCSA Term)

The term `verification' or `verify' means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier and lot number and expiration date assigned to the product by the manufacturer or the repackager.

There are three potential methods to do product verification:

1. Manual process in which a trading partner contacts a manufacturer via phone or email to verify that the product identifier is legitimate per the manufacturers serial number records.

2. Automated process in which a trading partner makes a service request to a database to verify that the product identifier is legitimate per the manufacturers serial number records.

3. Manufacturer provides the list of legitimate serial numbers that were shipped to a trading partner and said trading partner matches a product identifier against the provided list of assumed legitimate serial numbers.


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XAVIER HEALTH