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MICHIGAN STATE UNIVERSITY

Enhancement of the Drug Supply Chain Security Act (DSCSA) Using RAIN RFID

A Pilot Study to demonstrate that the medication supply chain challenges can be solved using Radio Frequency Identification (RFID), leading to improved Patient Safety

The Axia Institute, April 2025 | By Dr. Bahar Aliakbarian, Ethan Claucherty and Gregg Ubben

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Executive Overview

The traceability of prescription drugs across the supply chain to improve patient safety by reducing counterfeits represents a grand challenge that industry and regulators have been working to address for decades.

In 1987, the Prescription Drug Marketing Act (PDMA) was passed to protect American consumers from counterfeit, adulterated, misbranded, subpotent or expired prescription drugs. The PDMA did this by requiring a drug pedigree (statement of origin) for wholesale distributors, while providing additional guidance aimed at reducing the diversion of prescription drugs across the supply chain.

Following the passage of the PDMA, numerous states, including most notably California, worked on the implementation of electronic Pedigree laws to strengthen the regulation of prescription drugs. These laws focused on requiring traceability measures with the goal of tracking the flow of prescription drugs from manufacturer to distributor, the pharmacy and the patient.[1] Unfortunately, managing the differences in laws from state to state wasn't a practical solution for a national supply chain of critical importance.

And in 2004, the U.S Food and Drug Administration (FDA) published **COMBATING COUNTERFEIT DRUGS A Report of the Food and Drug Administration** highlighting the scope of the counterfeit prescription drug problem. This report included several recommendations for strengthening the prescription drug supply chain, and offered potential enhancements while specifying Radio Frequency Identification, or RFID as a technology capable of providing prescription drugs with the electronic pedigree that had previously been required by PDMA.[2]

Subsequent traceability requirements were codified in 2013 through Title II of the Drug Quality and Security Act (DQSA), known as the Drug Supply Chain Security Act or DSCSA. The passage of this law facilitated, among other things, the traceability of prescription drugs by requiring that a 2D data matrix barcode be affixed to the lowest saleable pharmaceutical unit containing the following information about each prescription drug:

1. The National Drug Code,
2. Serial Number,
3. Lot Number, and
4. Product Expiration Date.[3]

The industry has worked diligently to implement this law across the supply chain since its passage. While the FDA implemented a stabilization period for a group of dispensers in 2023, the law is now officially in effect. The decade-long implementation period for this law provided many opportunities to identify ways to improve the effectiveness of the law's intended outcome, including the

[1]Prescription Drug Marketing Act (PDMA) Requirements – Questions and Answers, November 2006, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/prescription-drug-marketing-act-pdma-requirements-questions-and-answers*
[2]Combating Counterfeit Drugs A Report of the Food and Drug Administration, February 2004. https://fda.report/media/77086/February-2004-Report.pdf
[3]Public Law 113-54 – 113th Congress, Nov. 27, 2013, https://www.congress.gov/113/plaws/publ54/PLAW-113publ54.pdf)

investigation of Radio Frequency Identification (RFID) as a data carrier to enhance the tracking of pharmaceuticals across the supply chain.

This whitepaper presents the findings of a comprehensive RFID-based pilot project led by the Axia Institute at Michigan State University, conducted in close collaboration with key industry partners. This is the first comprehensive initiative aimed at evaluating the scalability and real-world applicability of RFID technology in achieving end-to-end traceability within the pharmaceutical supply chain. RFID was originally identified as a technology capable of delivering electronic pedigree information for all tagged pharmaceuticals. This initiative builds upon the success of Phase 1 (completed by the Axia Institute in 2023), which demonstrated the technical feasibility of applying RFID to various drug formulations and packaging types in a laboratory setting.

Phase 2 significantly expanded the scope to test the robustness and interoperability of RFID in operational environments, aligned with GS1 standards and the U.S. FDA's DSCSA requirements. For the first time, tests were conducted using four full pallets of pharmaceutical products—with varying formulations and packaging sizes—across diverse environments, including the Axia Lab (simulating the manufacturer and pharmacies) and Cencora's Williamston Distribution Center.

A pivotal component of the project was the development of the Axia Observer Platform, an IoT-based software solution designed to track materials across the supply chain using both RFID scans and Electronic Product Code Information Service (EPCIS) supply chain event data. The platform enables both macro-level flow visualization and individual unit-level traceability, providing unmatched transparency throughout the product journey.

Thanks to the invaluable support of our industry partners—who contributed both funding and domain expertise—the project was able to simulate complex, real-world distribution scenarios. Four full pallets of pharmaceutical products were tagged at their sellable units and scanned at critical handoff points, including manufacturer outbound and wholesaler inbound stages. Products were then reorganized into six non-homogeneous formulations using different "recipes," further validating the technology's ability to maintain traceability even in mixed-handling environments.

Phase 2 Outcomes:

100% Traceability
achieved across the supply chain.

- 6,920 units were tracked through the supply chain using RAIN RFID.
- Exceptions were automatically identified and corrected in real-time thanks to the instantaneous feedback from the RFID system.
- RFID's value as a scalable complement to barcoding was demonstrated.

6,920
Units
tagged and tracked.

100%
of Human Errors
identified by RFID and corrected in real-time.

- Real-time data integration enabled proactive compliance and recall readiness.
- The pilot demonstrated readiness for DSCSA-aligned digitization of the pharmaceutical supply chain at scale.
- RFID enhances People ROI by requiring minimal training for effective operation, reducing physical exertion and manual labor, fostering job satisfaction by enabling employees to focus on meaningful customer interactions, and increasing overall workforce productivity by repurposing low-value tasks to high-value activities.
- The CCL eAgile Software successfully simulated the local site's ERP system.
- Axia's Observer Platform was developed and tested as an outside centralized platform to provide oversight of the supply chain. If a tag ID changed, it could be identified in real-time by Axia's Observer Platform.

This work represents a significant step toward building a more secure, error-proof, and digitally integrated pharmaceutical supply chain—one that can track and record product information at every stage, from production through distribution to the point of sale. The rich data captured through this system will also serve as the foundation for developing advanced analytical tools, enabling real-time decision-making, proactive risk management, and continuous improvement in supply chain performance.

Section 1: Introduction

Background

Interoperable tracing enables end-to-end visibility in the supply chain by using machine-readable labels or tags to track the movement of products and materials. This capability significantly enhances safety, security, and operational efficiency, particularly in regulated industries such as pharmaceuticals. Various data carriers, including barcodes, QR codes (specific type of 2-dimensional barcode), and RFID tags, facilitate this process. Unlike barcodes and QR codes, which require direct line-of-sight scanning, RFID tags allow automated, bulk reading of items, even when enclosed in packaging. This makes RFID a powerful tool for tracking pharmaceuticals across the supply chain.

Passive Ultra High Frequency (UHF) RFID tags, also known as RAIN RFID, are particularly well-suited for pharmaceutical applications. These battery-free tags have limited storage capacity but can encode critical product information, such as the lot/batch number and expiration date, in EPC memory. By leveraging RFID, supply chain stakeholders can enhance product traceability, improve recall management, and reduce inefficiencies. Despite its proven effectiveness, RFID adoption in the pharmaceutical supply chain has been slow. Key barriers include technical challenges related to environmental conditions (e.g., product composition, packaging materials, interference from other technologies) and integration complexities with existing supply chain processes and infrastructure.

To address these challenges, a multi-phase pilot project was conducted by Axia in collaboration with industry partners. Phase 1 of this pilot series demonstrated the technological feasibility of RFID in pharmaceutical traceability, achieving a high readability rate across various product compositions and packaging formats. Phase 2 focuses on scalability, evaluating how RFID can be seamlessly integrated into real-world industry workflows while defining a roadmap for widespread adoption.

This whitepaper presents the results of pilot Phase 2, highlighting the effectiveness of RFID for pharmaceutical track-and-trace, key lessons learned, and recommendations for industry-wide implementation.

1.2 Industry Partnership and Their Involvement

Partnership with industry experts was crucial from the inception of this pilot project. While the involvement of Pilot Advisory members was limited to shaping the Phase 1 study, their partnership and financial support were instrumental in shaping and finalizing Phase 2 of this project.

ANTARES VISION GROUP

Antares Vision Group provides solutions for digitalization and innovation in various sectors, such as pharmaceutical, food and beverage, while focusing on the digitization of rural territories.

Barcoding

Barcoding Inc. is one of the largest integrators and resellers of supply chain data capture and mobile tech solutions.

Cencora (formerly AmerisourceBergen) is one of the largest pharmaceutical wholesalers in the US. Phase 2 tests were conducted at one of Cencora's warehouses in Williamston, MI. This real-world testing environment provided sufficient evidence to demonstrate the technical feasibility of RFID tags being readable in a warehouse full of products and interference. Moreover, it helped determine how RFID could be integrated into their current operations.

CCL eAgile is a leader in RFID labeling and software. Tests were conducted using tags provided by CCL eAgile (qualified during Phase 1) and an automated RFID conveyor system for reading the products.

Fresenius Kabi (FK) is a leader in anesthesia drugs and RFID source tagging. FK provided four different pallets of "near-to-expiry" drugs, making this pilot a demonstration of a real-world environment.

GS1 US is a leader in global standards providing a common digital language to seamlessly communicate trusted data across the supply chain.

IntelliGuard is a leader in developing medication inventory management solutions to help hospitals and health systems continuously improve the environment of safety around every medication decision.

Section 2: Execution Plan

2.1 RFID Tags

Passive UHF RFID tags from CCL eAgile were used (Figure 1). This tag was demonstrated to be the most efficient tag among the three tags tested in Phase 1 of this pilot. Tags were encoded according to the GS1 TDS 2.X Standard with the product's GTIN, Serial, LOT, and Expiry on the chip.

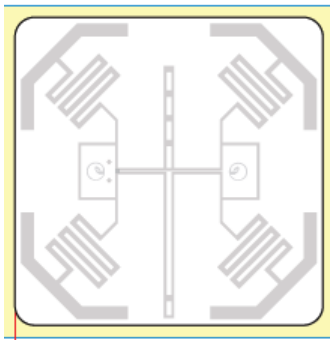


Figure 1 – 50x50 mm RFID Label

2.2 Pharmaceutical Products and Totes

Four pallets containing various pharmaceutical products from Fresenius Kabi were tested during this pilot. For a detailed list of the products, please refer to Appendix A. Additionally, two different tote sizes from Cencora were utilized in this project, as illustrated in Figure 2.

Figure 2 – Large (Left) and Small (Right) Totes from AmerisourceBergen (Cencora).

2.3. Equipment to Capture Read Observations

An RFID-enabled tunnel from CCL eAgile (Figure 3) was utilized to capture data from the RFID tags at the item, tote, and case level. The system validated serialized contents against shipping documents. A key feature of the CCL eAgile conveyor system is its ability to isolate RFID tags during scanning, which helps prevent stray reads. This isolation was critical to maintaining the integrity of the read events. The RFID Tunnel settings are provided in Table 1.

Figure 3 – RFID-Enabled Tunnel

Table 1. RFID-Enabled Tunnel Settings									
Antenna Port Settings			*Trigger Settings*		*Advanced Settings*				
Antenna 1,2,3,4,5,6 Power (dBm)	RF Mode	Dwell Time (ms)	Start Read When…	Stop Read After (s)	Antenna Singulation	State Aware	Inventory State	Flag State	Tag Population
21 at Wholesaler 22 at Pharma	Maximum Data	200	Start + GPI goes high	2.5	Session 1	Active		All	150
20, 20, 24, 25		200	Start + GPI goes high	1.5	Session 1	Active	A	All	150

2.4 Experimental Procedure

2.4.1. Tests to Identify the Tag Placement

A series of preliminary tests were conducted to determine the optimal placement of RFID tags on various saleable units. The initial step involved identifying potential tag locations based on the "RFID Tagging Location Guideline" provided by Auburn University's RFID Lab. Following a thorough review of these guidelines, we selected one location for the RFID tag on both Oxytocin and Hydralazine units, two locations for Ceftriaxone units, and eight potential locations for Iodixanol units. For each identified tag location, a threshold sweep was performed within a C50 Voyantic anechoic chamber using Antenna 1, with the table rotated at 0° and 90°. The results from these sweeps were averaged and compared to determine the optimal tag placement. The final deciding factors for tag location included achieving a read range greater than 2 meters (6.56 feet), which aligns with typical asset management applications, and identifying the tag location with the lowest tag sensitivity. The results of Tag Placement Tests are detailed in Appendix B.

2.4.2 End-to-End Flow & Execution Steps

The pilot project simulated a real-world pharmaceutical distribution process across three key nodes in the supply chain as shown in Figure 4: Manufacturer (Axia Lab), Wholesaler (Cencora, Williamston, MI), and Pharmacies (Axia Lab).

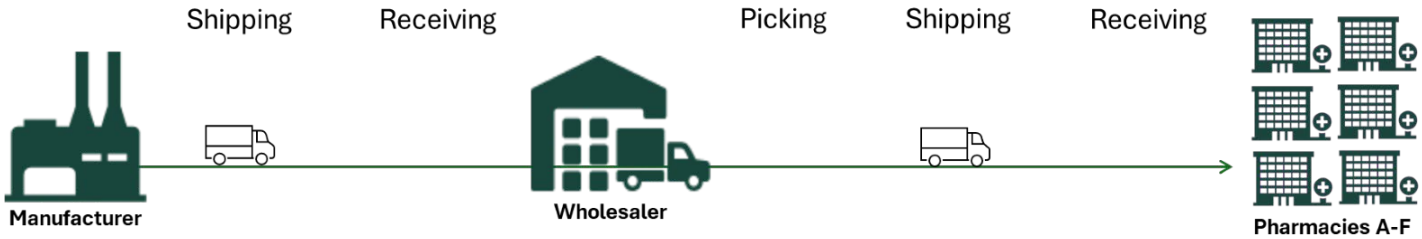


Figure 4: Pharmaceutical Supply Chain Representation and Different Steps Included in this Pilot.

To avoid interference with daily business operations at the various companies involved, the CCL eAgile Software was used to simulate the different companies involved in the supply chain. The CCL eAgile Software was connected to the RFID scanners for collecting Shipping (Aggregation) and

Receiving (Disaggregation) Scans. The CCL eAgile Software also generated the EPCIS Files used for transfers between companies.

Moreover, Axia's Observer Platform provided oversight, real-time monitoring, and compliance verification. The Axia Observer Platform is a centralized platform that operates outside of the scanning hardware, and aggregates and monitors all supply chain events, ensuring cross-organizational transparency and end-to-end traceability.

At the Manufacturer – Axia Lab
(Simulating Fresenius Kabi)

SHIPPING PROCESS:

- Four pallets of pharmaceutical products were received from Fresenius Kabi and stored at the Axia Lab.
- A total of 6,920 individual lowest saleable units (LSUs) were tagged and scanned, assigning a unique Serialized Global Trade Item Number (SGTIN) to each.
- LSUs were aggregated into Cases, each assigned a Serial Shipping Container Code (SSCC).
- Cases were stacked into pallets. Full pallet composition details are available in Appendix A.
- All SGTIN and SSCC scans were consolidated to generate an EPCIS event file using the CCL eAgile Software.
- Two standardized GLN locations were used to simulate the Manufacturer-to-Wholesaler shipment:
  - Manufacturer (Fresenius Kabi): 0363323.11111.0
  - Wholesaler (Cencora): 0952050.11111.0
- The EPCIS file was electronically transmitted to the CCL eAgile Software, which acted as Cencora for the Pilot and then uploaded into the Axia Observer Platform.

✔ *Validated serialization and aggregation at origin*

✔ *EPCIS-enabled data sharing with partners*

At the Wholesaler – Cencora (Williamston, MI)

RECEIVING PROCESS:

- Each case from the pallets was scanned using the CCL eAgile RFID-enabled Tunnel.
- Scans were immediately verified onsite against the EPCIS file using the CCL eAgile Software (Wholesaler-Receiver Mode).

- Simultaneously, all data was transmitted to the Axia Observer Platform for an external compliance check.
- Upon successful cross-verification of scan data with the EPCIS file, the inventory was deemed complete, and the Picking Process commenced.

PICKING PROCESS:

- Cases were opened and individual LSUs were mixed into totes (both small and large) according to pre-defined mixing rules.
- Each tote was assigned a new SSCC, representing the aggregated contents.
- Formulation details (picklist) for each tote are provided in Appendix C.
- Totes were grouped into six unique pharmacy orders, simulating shipments to six different pharmacy locations. Order configurations can be found in Appendix D.

SHIPPING PROCESS:

- Each tote and its corresponding SSCC were scanned using the CCL eAgile RFID-enabled Tunnel, aligned with each pharmacy order and scheduled shipment time.
- Scans were immediately validated against tote formulations via the CCL eAgile Software (Wholesaler-Shipping Mode).
- In parallel, data was sent to the Axia Observer Platform for compliance verification.
- Upon successful validation, pharmacy orders were finalized, pallets were wrapped, and shipments were prepared for dispatch.
- All six EPCIS files, one per pharmacy order, were generated by the CCL eAgile Software and uploaded into the Axia Observer Platform for real-time monitoring and compliance verification.
- The CCL eAgile Software, taking the role of each pharmacy, uploaded the six EPCIS files to prepare for receiving.

✔ *Proved accuracy in mixed-product handling.*

✔ *Enabled order-level traceability and compliance auditing.*

At the Pharmacies – Axia Lab (Simulating Pharmacy Endpoints)

RECEIVING PROCESS

Performed one pharmacy at a time:

- Each tote was scanned upon arrival using the CCL eAgile RFID-enabled Tunnel.
- Scans were validated in real time against the expected EPCIS file using the CCL eAgile Software (Pharmacy [A…F]-Receiver Mode).
- Simultaneously, data was shared with the Axia Observer platform for external cross-verification.
- Once the scan data matched the expected inventory from the EPCIS file, the receiving process was successfully completed and the next pharmacy was set up to receive.

✅ *Confirmed end-to-end visibility and traceability*

✅ *Final inventory reconciliation completed successfully*

Section 3: Key Findings & Results

Over the course of the pilot, a total of 6,920 products were successfully tracked, achieving 100% traceability using RFID. Throughout the entire process, approximately 20 exceptions were detected. Each was quickly identified and resolved in real-time, preventing any accumulation of errors or data loss across the entire supply chain. These results confirm the significant value of RFID as a complementary technology to traditional barcoding, providing enhanced visibility, improved interoperability, and increased resilience throughout the pharmaceutical supply chain.

3.1. Digital Oversight: Dual Software Architecture for End-to-End Visibility

To enable seamless monitoring of both product flow and data integrity throughout the supply chain, two complementary software platforms were deployed.

The first, the CCL eAgile Software developed by CCL eAgile, is tightly integrated with the CCL eAgile RFID-enabled Tunnel and provides real-time, on-site monitoring of RFID read observations. This system ensures immediate validation of data during scanning operations and plays a vital role in operational accuracy at the local level.

Secondly, the Axia Observer Platform was developed by the Axia Institute as an independent, third-party observability layer. Operating outside of the scanning hardware, the Axia Observer Platform

functions as a neutral, centralized platform that aggregates and monitors all supply chain events, ensuring cross-organizational transparency and end-to-end traceability (see Figure 5).

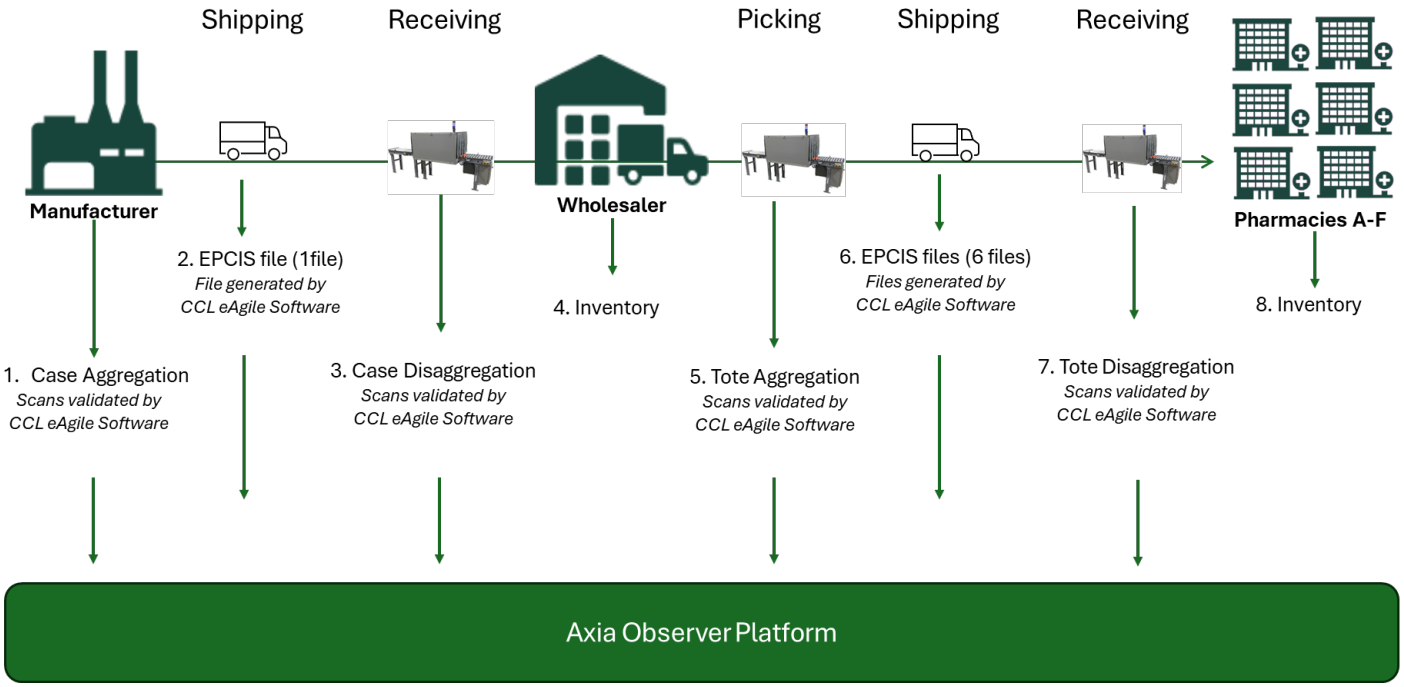


Figure 5: RAIN-enabled Pharmaceutical Supply Chain Representation including CCL eAgile Software to capture RFID Read Observations, and the Axia Observer Platform to Monitor Supply Chain Events.

Both the CCL eAgile Software and Axia Observer Platform were utilized in parallel to monitor product integrity and traceability throughout the supply chain. The CCL eAgile Software interfaced directly with RFID scanners to capture Shipping (Aggregation) and Receiving (Disaggregation) local scans, generating EPCIS files in the process. Meanwhile, the Axia Observer Platform continuously collected supply chain event data, offering a seamless, real-time monitoring platform that tracked product movement across various locations.

3.2 Key Capabilities of the Axia Observer Platform (Software-as-a-Service)

The Axia Observer Platform provides advanced monitoring, validation, and visualization features that enhance the integrity and usability of EPCIS event data by looking across the entire supply chain:

✓ **Real-Time Monitoring**
The Monitor Page displays real-time updates when new observations or events are posted from reader software, allowing supply chain stakeholders to observe product movement as it happens.

✓ **Event Replaying and Review**
Users can replay to past events to simulate original reads or view event activity directly, offering flexible ways to review historical transactions.

✓ Error Highlighting and Validation

- Any uncommissioned SGTINs or SSCCs (not included in the EPCIS file) are highlighted in red to flag inconsistencies.
- During receiving, any missing (e.g., unscanned tags) SGTINs or SSCCs according to the EPCIS Aggregation definitions are detected and flagged.
- During receiving, any extra (e.g. additional scanned tags) SGTINs or SSCCs according to the EPCIS Aggregation definitions are detected and flagged.

✓ Master Data Integration

Product names are automatically retrieved using the Master GTINs embedded in the EPCIS files, providing intuitive readability of events.

✓ Summary Reporting

Summary counts and tag status indicators are included on the Monitor Page to quickly assess shipment completeness and compliance.

✓ Anomaly Detection

- Missing event tags within a shipment are flagged against expected aggregations, enabling proactive correction before errors propagate downstream.
- Extra event tags within a shipment are flagged against expected aggregations, enabling proactive correction before errors propagate downstream.
- Tags that have not been commissioned are flagged against expected EPCIS definitions.
- SGTINs and SSCCs arriving at the wrong location due to an error in shipping.
- SGTINs and SSCCs that have moved from one location to another location without prior notification are flagged. The Sender of one EPCIS Shipping event should have been the Receiver in another EPCIS Shipping event for each of the SGTINs and SSCCs unless the Commissioning event states it was created by that Sender.
- Use or movement of a SGTIN or SSCC without performing a disaggregation event, which can be implied when the SGTIN or SSCC is a first-level child to an aggregation.

✓ Macro Flow Visualization

A dynamic Sankey-style diagram (see Figure 6) offers a big picture visual representation of product flow between supply chain partners, helping stakeholders understand bottlenecks, handoff points, and packaging at a glance.

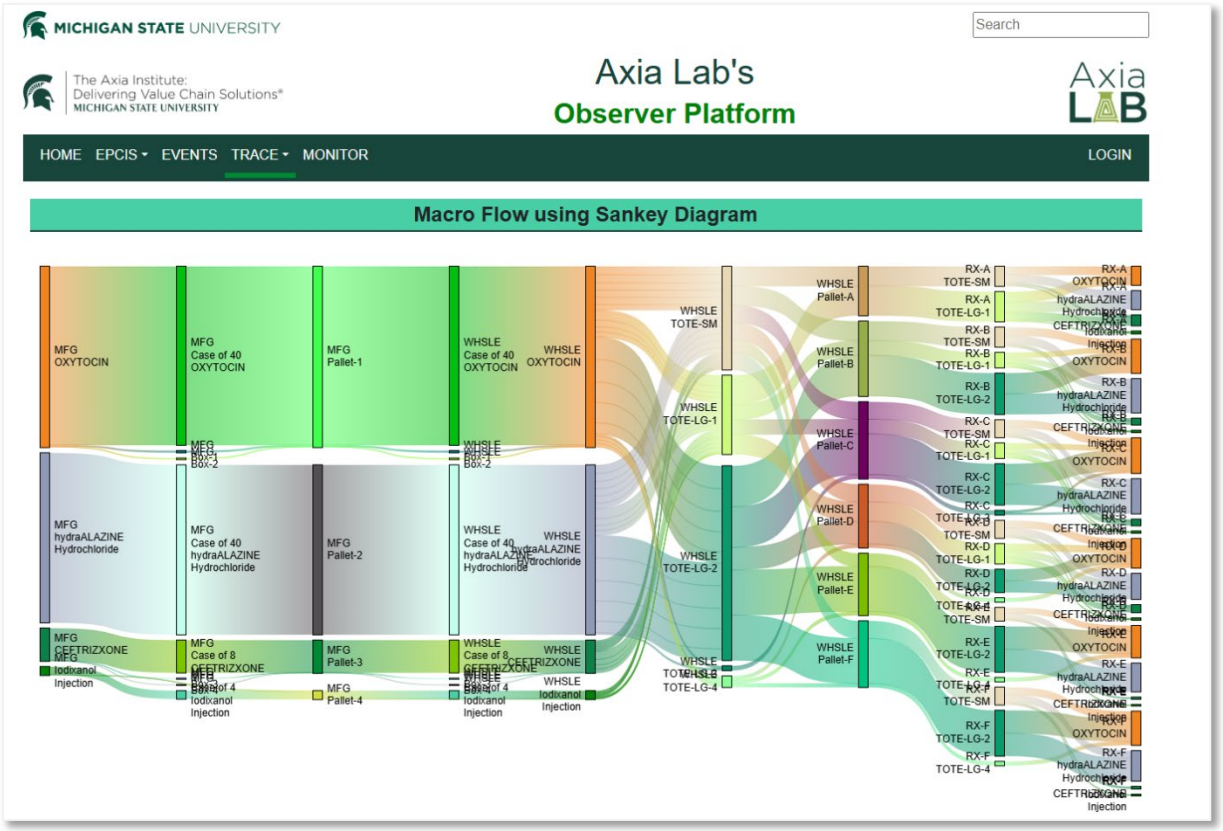
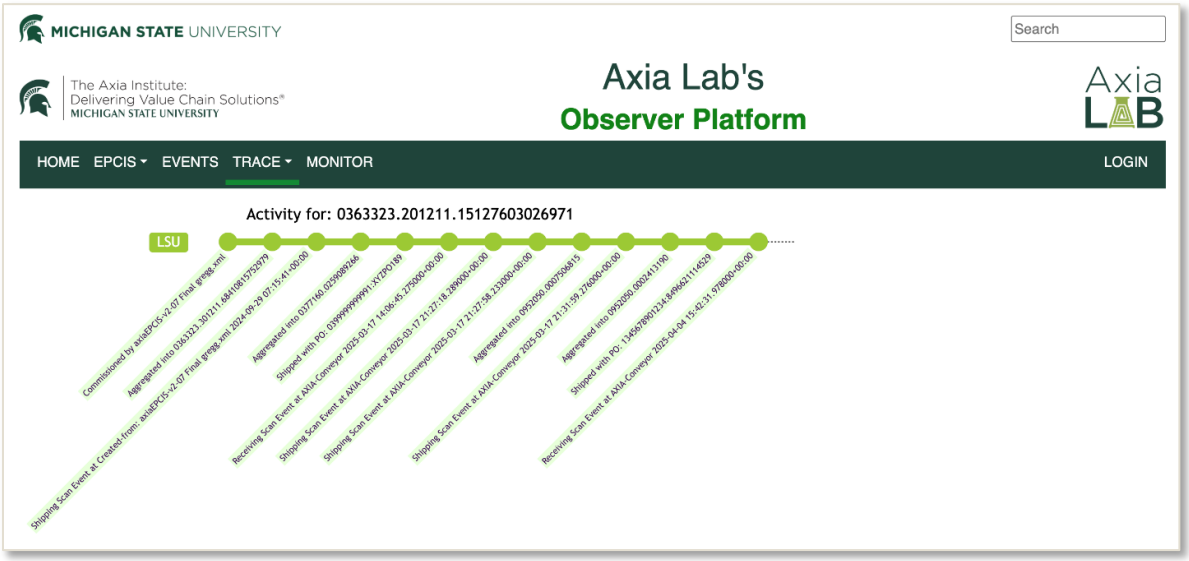


Figure 6: Macro Flow Visualization of the products' Movement Across the Supply Chain using Axia Observer Platform

✓ *Product Flow Visualization:*

A dynamic Git Graph-style diagram (see Figure 7) provides a visual representation of a single product's flow through the supply chain, helping stakeholders understand packaging, handoff points, and anomalies.



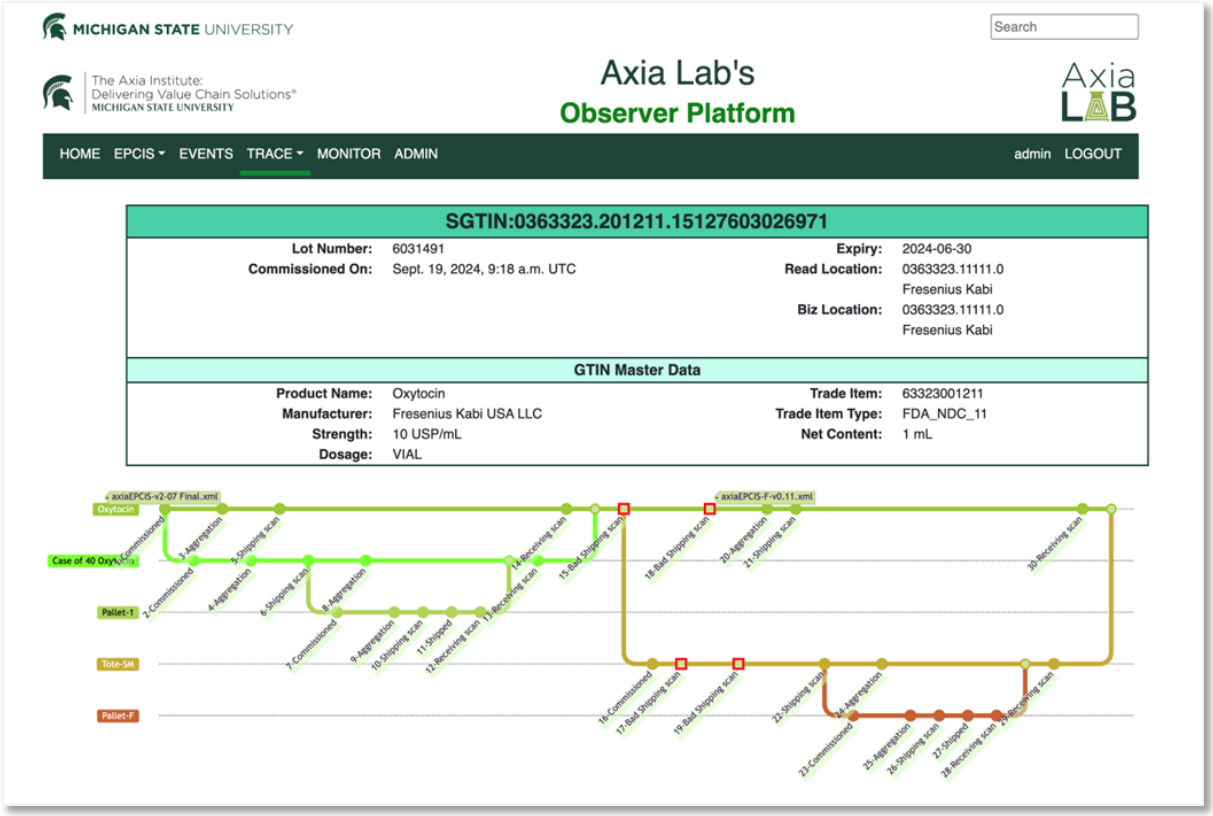


Figure 7: Product Flow Visualization of a Single Product (SGTIN or SSCC) Movement Across the Supply Chain using Axia Observer Platform

Overall, the deployment of the Axia Observer Platform improves the efficiency of operations across the entire supply chain because it can:

- Track, visualize, and identify anomalies across all companies participating in the supply chain.
- Reduce manual tracking efforts.
- Provide real-time updates on product location and status.
- Help to identify bottlenecks or errors in real-time by reducing the accumulation of inefficiencies in the supply chain.
- Provide an end-to-end transaction history for every SGTIN or SSCC, facilitating identification and elimination of recalled products.
- Identify if products are showing up at unexpected locations, such as product(s) expected at Pharmacy A arriving at Pharmacy B.

Section 4: Business & Industry Implications (Practical Takeaways)

The implementation of RFID technology across the pharmaceutical supply chain holds tremendous potential for operational improvements at multiple nodes. The DSCSA requires that pharmaceuticals be tagged with human-readable information and 2D barcodes containing the Global Trade Item Number (GTIN), Serial, Lot/Batch Number and Product Expiration Date at the product's lowest

saleable unit. While barcodes enable the electronic capture of pharmaceutical data across the supply chain, this technology requires line-of-sight access for items to be scanned.

RFID tags can store additional data beyond what is possible with a barcode. RFID can provide precise, real-time monitoring of product location. Additional product-specific information, such as location and temperature, can be captured while providing real-time integration with existing ERP and inventory management systems. Most importantly, RFID tags do not require a direct line of sight to be read, reducing labor requirements at key points in the supply chain and eliminating any unaccounted-for inventory due to line-of-sight scans that may have been missed.

The research completed in Phase 2 of Axia's End-to-End RFID study demonstrates the potential for streamlining the process of receiving pharmaceuticals into a warehouse distribution environment. Using RFID, shipments need only pass through an RFID-enabled Tunnel to be accepted and can be reconciled against a purchase order to ensure that all products have been received. Reconciling orders more efficiently via RFID has the potential to increase operational efficiency by improving inventory accuracy and strengthening regulatory compliance.

Representatives from Cencora and CCL eAgile, two of the business partners who participated in Phase 2, explain the potential impact RFID could have on the industry:

> "RFID certainly shows promise, especially given some of the challenges with line-of-sight technology and barcode degradation that we're already seeing today. In an ideal world, we'd be able to leverage RFID readers to capture all critical DSCSA data.
>
> Given that we sell over 1B units a year, often close to 5M units a day, this would enable us to be much more cost-efficient in how we process orders, as well as ensuring complete order accuracy for our customers.
>
> That said, for this to become a reality for the industry, we have to identify what critical mass looks like and other value drivers to incentivize manufacturers to tag their products. I don't need 100% of all products tagged, but certainly need something more than 25% to make a positive NPV. I continue to be encouraged by the results, and do believe that if, and when, we start seeing data integrity issues with DSCSA that start causing product disruptions, we'll have no choice but to turn towards RFID as a stepwise improvement in technology."
>
> **Matt Sample**
> SVP, Manufacturer, Quality, and Replenishment Operations
> Cencora

> "The important message is that the RFID system was able to achieve 100% accuracy at each point of the medication supply chain through real-time exception correction. In addition to accuracy, the pilot was able to achieve a validated chain of custody. The results show that RFID provides a strong and accurate chain of custody, demonstrating that the objective of a highly secure medication supply chain is now achievable."
>
> **Gary Burns**
> Business Director
> *CCL eAgile*

RFID can also refine other supply chain processes, such as the unpacking and repacking of pharmaceuticals for distribution to those further downstream in the supply chain. Specifically, Phase 2 of the pilot further demonstrated how integrating RFID technology into the pharmaceutical supply chain can improve business processes by enabling real-time anomaly detection and preventing the accumulation of inefficiencies. The RFID ecosystem used for this work also showed the ability to seamlessly integrate with the local company's ERP system, as simulated by the CCL eAgile Software used in this pilot.

4.1 At the Local Company's ERP System:

- Using RFID tags, an already packed shipment can be checked against the purchase order to ensure all the products (GTINs) are present.
- The specific product (SGTIN), as read via RFID tags, can be associated with the order, including the Lot Number and Expiry Date, for detailed tracing through the supply chain.
- Any extra or missing products identified during RFID scanning can be pinpointed and fixed locally prior to shipment.
- When scanning a received shipment, the Company's ERP system can confirm that every product is accounted for without opening the box or case.
- In transit, tampering can be detected by local receiving scans to see if products are missing, or extra products have been added.

4.2 Using Axia's Observer Platform

Unexpected movement of product can be identified in the following scenarios:

- If the previous receiving location does not match the shipping location.
- If the product was not taken out of the box (disaggregation).
- If an RFID tag Identifier has been changed on a product.
- If there is any spoiled product or tampered product in one box/case which could impact other products (suspicious by association).
- If an RFID tag is scanned more than once or used after decommissioning.
- If SGTINs/SSCCs are duplicated or used after decommissioning.

As additional industry participants begin implementing RFID across the pharmaceutical supply chain, Axia's Observer Platform can be deployed as a Software-as-a-Service (SaaS) tool to ensure that events are properly tracked across all companies participating in the supply chain and integrate properly with an organization's existing ERP or inventory systems. This platform, integrated within an RFID ecosystem, can also be applied to similar supply chains, such as the food supply chain, to enhance item-level traceability and reduce operational costs associated with human errors during receiving, order picking, and shipping.

The findings of this RFID-based study also have significant implications for Controlled Substance handling and offer a way to better secure this sector of the pharmaceutical supply chain. RFIDs' real-time location tracking can help manufacturers, distributors, and dispensers prevent drug diversion and demonstrate compliance to regulators. Beyond the data required by DSCSA, RFID tags can also support the reporting mandated by the Drug Enforcement Administration (DEA) via the Automation of Reports and Consolidated Ordering System (ARCOS), which tracks all Controlled Substance transactions from manufacturer to patient.

Section 5: Next Steps (Roadmap Overview)

The successful completion of Pilot Phase 2, along with the demonstrated benefits of RFID integration, encourages Axia to continue its efforts and advance the technology to the next phase, extending its application to hospitals and enabling item-level traceability up to the patient. An overview of Axia's approach is illustrated in Figure 8.

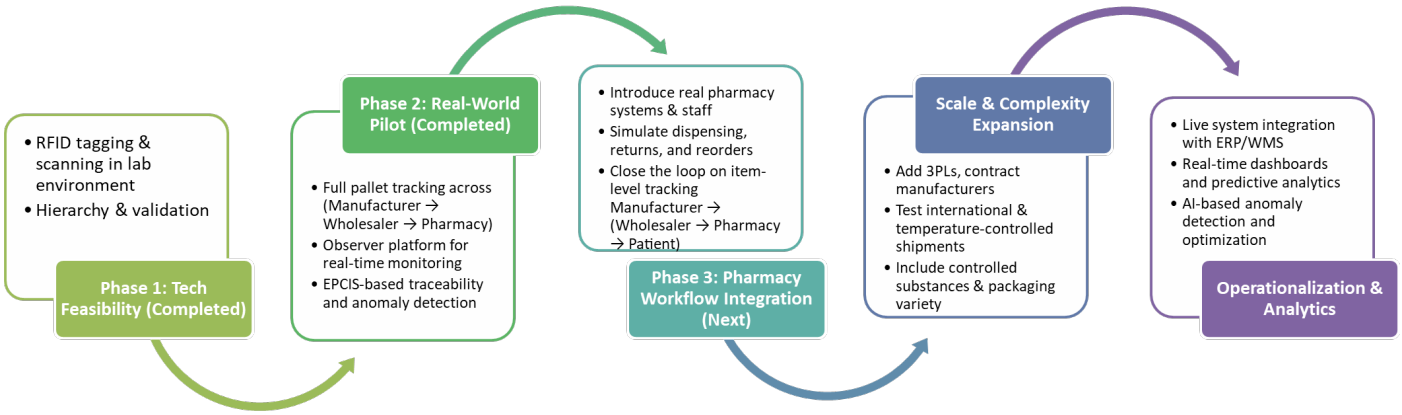


Figure 8: Next Steps and Project Roadmap

Acknowledgements

The Axia Institute team extends its sincere appreciation to the following "Pilot Advisory Group" for their unwavering support and invaluable guidance throughout this project.

Gary Burns
CEO,
CCL eAgile Inc.

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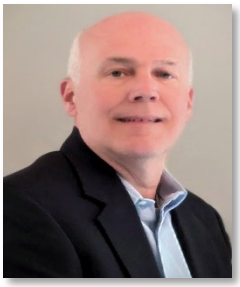

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About The Axia Institute

As a premier value chain innovation center, The Axia Institute® is dedicated to improving Healthcare, Food & Agriculture and Advanced Manufacturing value chains through industry collaboration, applied research and education. Established by Michigan State University in 2013 in Midland, Mich., the Axia Institute and its Axia Lab are part of MSU's Office of Research and Innovation.

More than 30 companies are member partners who align to three industry-specific consortia groups to collaborate and solve grand challenges that would be difficult to resolve alone. Developing sustainable and revolutionary solutions is driven by our expertise in value chain digitization, value chain optimization, traceability, circular economy, packaging design, fundamental R&D, and talent development.

The Axia Lab™ is an impartial testing and research lab advancing innovative and sustainable value chain solutions. The Axia Lab, which opened in 2021, specializes in testing RFID-tagged items

according to GS1 standards. It is accredited by the ANSI National Accreditation Board (ANAB) to ISO/IEC 17025:2017 in the field of testing. In the pursuit of research excellence, the Axia Lab created a new test protocol for grading the performance of RFID tags used on healthcare vial items in 2024. These proposed grades are the first developed testing methodology for Axia Lab and are the first globally accepted grading system adopted by GS1 in the healthcare/ pharmaceutical category within the Tagged-Item Performance Protocol (TIPP).

Appendix A - List of Pharmaceuticals

Four Total Pallets

Pallet 1. Oxytocin: 1 pallet= 80,000 units = 3200 units of sale packs

Pallet 2. Hydralazine: 1 pallet= 75,000 units = 3,000 units of sale packs

Pallet 3. Ceftriaxone: 1 pallet =14,400 units= 576 units of sale packs

Pallet 4. Iodixanol: 1 pallet= 1,440 units = 144 units of sale packs

Figure A. Four Pallets of FK products Stored at the Axia Lab.

Appendix B – Tag Placement Test Results

Figure B. Salable Unit Tag Placement: Top Left: Oxytocin, Top Right: Hydralazine, Middle: Ceftriaxone, Bottom: Iodixanol.

Table B. Selected Tag Placement Performance Results

Product	*Tag Location*	*Average Tag Sensitivity (dBm)*	*Average Max Read Range (ft.)*	*Average Min Read Range (ft.)*
Oxytocin	Top	-11.48	27.14	23.63
Hydralazine	Top	-11.13	26.25	23.04
Ceftriaxone	Top	-9.63	21.68	16.91
Iodixanol	Top	-11.45	26.26	18.80

Appendix C -Tote Formulations

TABLE C. Tote Formulations

	Small Tote	*Large Tote*			
	Formulation 1	*Formulation 1*	*Formulation 2*	*Formulation 3*	*Formulation 4*
Oxytocin*	8	10	40	40	64
Hydralazine*	8	10	40	32	-
Ceftriaxone*	2	8	-	-	-
Iodixanol*	1	1	-	-	-
Number of Totes	96	48	43	1	3

* Numbers refer to the lowest saleable units (LSUs) in a Tote

Figure C. Representation of a Large Tote (Left) and Small Tote (Right) filled with different products.

Appendix D - Pharmacy Orders

TABLE D. PHARMACY ORDERS

	Small Tote	Large Tote			
	Formulation 1	*Formulation 1*	*Formulation 2*	*Formulation 3*	*Formulation 4*
Pharmacy A *Amazing Pills Pharmacy*	18	18			
Pharmacy B *Better Health Boutique*	18	9	9	-	-
Pharmacy C *Better Health Boutique*	16	9	9	1	-
Pharmacy D *Better Health Boutique*	16	12	5	-	1
Pharmacy E *Easy Meds Express*	12	-	10	-	1
Pharmacy F *Feel Better Pharmacy*	16	-	10	-	1
Total Number of Totes	96	48	43	1	3

*Numbers refer to total number of totes