DSCSA vs. FSMA: Why RFID Is a Key Enabler for Compliance with DSCSA and FSMA

A Whitepaper

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Introduction

The FDA (Food and Drug Administration) is a federal agency of the United States Department of Health and Human Services that is responsible for protecting and promoting public health through the control and supervision of a diverse group of consumer products. The major product categories that fall under the FDA's jurisdiction are food, pharmaceutical, and medical devices. The Drug Supply Chain Security Act (DSCSA) and the Food Safety Modernization Act (FSMA) are two critical pieces of legislation that have been implemented by the FDA to improve the safety and security of the drug and food supply chains in the United States. While the DSCSA is focused on prescription drugs, the FSMA focuses on food safety. Both acts have different mandates and requirements, but they share the same goal of protecting public health and safety by ensuring the safety and security of their respective supply chains.

This whitepaper will provide an overview of the DSCSA and FSMA mandates and requirements, highlighting the similarities and differences between the two acts. It will also explore the current initiatives that are in place for both acts to improve compliance and enhance the safety and security of the supply chains. Furthermore, this whitepaper will introduce Avery Dennison's and Axia Institute's perspectives on the application of Radio Frequency Identification (RFID) to enhance the traceability of products and improve compliance with both acts. Although there are different technical and operational steps that are distinct and need to comply with specific requirements of each, this approach will offer benefits such as real-time monitoring, improved data accuracy, and reduced cost of operations. With the increasing complexity of supply chain management, this proposed approach offers a promising solution to help ensure the safety and security of both the food and drug supply chains.

The FDA's DSCSA Mandate: Timeline, Requirements

The Drug Quality and Security Act (DQSA) is a law enacted by Congress on November 27, 2013. The law includes Title II of the DSCSA, which outlines steps to achieve interoperable, electronic tracing of products at the package level to identify and trace certain prescription drugs as they are distributed in the United States. The goal is to protect consumers from exposure to counterfeit, stolen, contaminated, or otherwise harmful drugs. The law also requires national licensure standards for wholesale distributors and third-party logistics providers, with annual reporting of licensure and other information to the FDA (DSCSA, 2013).

The DSCSA sets out requirements for manufacturers, re-packagers, wholesale distributors, dispensers, and third-party logistics providers involved in the drug supply chain. In 2013 regulations were created with 2015 as the ideal target to implement product serialization. However, due to the complexity of the requirement, the original time set was pushed back to 2018. The FDA is working with trading partners and stakeholders to ensure the effective implementation of these requirements, including the development of standards and the tracing system for drug products. For the first phase of the DSCSA requirement, manufacturers/repackagers must include product identifiers (e.g., affixing 2D barcode) on saleable units packaged before November 2018. Distributors were to only engage in products with product identifiers as of November 2019, and dispensers were to only engage in products with product identifiers starting November 2020. All entities within the supply chain are required to share serialized data electronically starting November 2023 (FDA recommends EPCIS or portals).

In summary, by November 2023, policies and procedures must be in place to allow for unit-level traceability of most prescription pharmaceutical products and all communications between trading partners, authorities, and dispensers must be conducted via a secure, interoperable, electronic system. DSCSA is still being implemented and brought to the forefront to this day in various phases or requirement deadlines (Figure 1).



FIGURE 1: UP-TO-DATE TIMELINE OF DSCSA REQUIREMENTS

Public-Private Partnership and Requirements

The FDA collaborates with stakeholders to secure the U.S. drug supply chain, and the Partnership for DSCSA Governance (PDG), is a sectorneutral, nonprofit organization that supports the effective and efficient implementation of DSCSA requirements for electronic, interoperable tracing, and verification of prescription drugs in the United States. The PDG includes a range of supply chain stakeholders, and the FDA participates on the PDG interoperable committee to discuss technical challenges or operational issues faced by trading partners and other stakeholders. These collaborative efforts aim to improve the integrity of the drug supply chain by preventing harmful drugs from entering the supply chain, detecting, and identifying harmful drugs, and responding rapidly and effectively when harmful drugs are found. The enhanced drug distribution security requirements will go into effect November 27, 2023, for tracing products at the package level.

Interoperability - The Key Component of the DSCSA

The DSCSA aims to achieve electronic, interoperable tracing of prescription drugs at the package level throughout the U.S. drug supply chain. This involves establishing a system that enables trading partners to exchange information about prescription drugs, including transaction information, transaction history, and a transaction statement back to the manufacturer for each unit sold. The system must enable efficient and secure communication among trading partners and support the identification and handling of suspect and illegitimate products. These interoperability requirements will be phased in throughout 2023. Table 1 discusses these requirements in much more detail and in chronological order. It should be noted that not all of the above-listed requirements apply to all stakeholders but are rather a generalized look at what is expected (refer to Table 1 for specific requirements).

TABLE 1: KEY REQUIREMENTS ENACTED AS A PART OF THE DSCSA (BEFORE PUSHBACKS)

Start Date	Trading Partner(s)	Requirement
11/27/2014	Third-party logistics	Report licensure and other information to FDA
07/01/2015	Wholesale distributors	Report licensure and other information to FDA
01/01/2015	Manufacturers, repackagers, wholesale distributors	Lot-level tracing: Providing transaction information, history, and statement
01/01/2015	Manufacturers, repackagers, wholesale distributors, dispensers	Establish a system for identifying and handling suspicious or illegitimate product
01/01/2015	Manufacturers, repackagers, wholesale distributors, dispensers, third-party logistics providers	Must be authorized as per the Food, Drug, and Cosmetic Act
07/01/2025	Dispensers	Lot-level tracing: Providing transaction information, history, and statement

FDA's FSMA Mandate: Timeline, Requirements

The FDA FSMA is a law that enables the FDA to focus on preventing food safety problems rather than reacting to them after they occur. It provides the FDA with new enforcement authorities to achieve higher rates of compliance with food safety standards and to better respond to and contain problems when they do occur. The law also directs the FDA to build an integrated national food safety system in partnership with state and local authorities. The FSMA is designed to address the significant public health burden of foodborne diseases, which affect about 48 million people, causing hospitalization and death each year in the United States. The implementation of the law will take time, and the FDA is committed to an open process with input from all stakeholders.

The guidelines and requirements set in place by the FDA to address various aspects of the food supply chain that are monitored and secured as a part of FSMA can be found in Table 2.

FOOD SUPPLY CHAIN ASPECT	GUIDELINE SCOPE
Prevention	 Mandatory prevention controls for food facilities Mandatory produce safety standards Authority to prevent intentional contamination
Inspection and Compliance	 Mandated inspection frequency Records access Testing by accredited laboratories
Response/Preventive Control upon Problem Encounter	 Mandatory recall Expanded administration detention Suspension of registration Enhanced product tracing abilities Additional record-keeping for high-risk foods
Imports	 Importer accountability Third-party certification Certification for high-risk foods Voluntary qualified importer program Authority to deny entry
Enhanced Partnerships	 State and local capacity building Foreign capacity building Reliance on inspections by other agencies

TABLE 2: FDA FSMA GUIDELINES AND REQUIREMENTS

Public-Private Partnership and Requirements

Achieving the goals of FSMA, as with the DSCSA, requires global partnership and collaboration. Creating an integrated global food safety network that includes government counterparts, international organizations, the food industry, growers, academic experts, and consumers is also essential. Attaining this level of integration and collaboration calls for enhancing operational partnerships with states and other government counterparts. At the same time, robust data integration and analysis systems should be built to support active partnerships and foster mutual reliance among trusted partners.

Advancing Public Health – The Key Component of the FSMA

The following outlines how the FSMA aims to advance public health in the present and going forward.

- Fosters broad, consistent industry implementation of modern preventive practices to reduce the risk of foodborne illness.
- Plays a central public health leadership role as a catalyst for innovation and action to improve food safety.
- Focuses on using a broad array of tools to ensure that firms are consistently implementing effective prevention systems that protect food safety.
- Uses an expanded oversight tool kit that includes traditional and new tools to ensure prevention systems are working properly.
- Expands the skills and capacities of the organizations' scientific, technical, and operational staff and changes its internal operational practices to enable the agency to make quick decisions and take immediate action when needed to protect public health.
- Improves the quality and quantity of data used to fully evaluate and make the most informed, risk-based decisions.

Similarities and Differences Between DSCSA and FSMA

DSCSA and FSMA tackle the traceability and security issues of pharmaceuticals and food products respectively but were implemented by the FDA for primarily the same reason – to protect public health and safety by ensuring the safety and security of the drug and food supply chains in the United States. Table 3 summarizes the requirement similarities and differences between DSCSA and FSMA.

TABLE 3: DSCSA and FSMA: PROTECTING U.S. DRUG AND FOOD SUPPLY CHAINS

DSCSA	FSMA
Applies specifically to the pharmaceutical industry and governs the supply chain for prescription drugs.	Applies to the food industry and governs the safety of food products.
Primarily focuses on the traceability of pharmaceutical products, requiring pharmaceutical manufacturers, distributors, and dispensers to track and trace prescription drugs throughout the supply chain.	Focuses on the prevention of foodborne illness and requires food manufacturers and suppliers to implement preventative measures such as hazard analysis and risk-based preventive controls.
Sets specific deadlines for the implementation of new requirements.	Has a longer implementation timeline and includes a variety of measures that will be transitioned over time.
Includes provisions for the sale of prescription drugs only to authorized distributors.	Focuses on the safety and security of the entire food supply chain, including imported foods.

Current DSCSA and FSMA Initiatives

Since the inception of the DSCSA and FSMA, several technology providers have focused on proposing and piloting solutions to facilitate the implementation of the FDA requirements. These initiatives are being developed at federal and other third-party levels, some of which are listed below.

DSCSA Pilot Project Program

The DSCSA Pilot Project Program was an initiative by the FDA to assist drug supply chain stakeholders, including the FDA itself, in developing an electronic, interoperable system that will identify and trace key prescription drugs as they are distributed throughout the United States. Under this program, the FDA collaborated with selected participants to research and evaluate technologies that could enhance the safety and security of the drug supply chain based on the requirements outlined in the law that will go into effect in November 2023. The program has concluded, and FDA made a final program report available to the public, which will allow all supply chain stakeholders to gain from the information gathered and learned from the DSCSA pilot project program. The selected program participants and their respective projects are listed in Table 4. The project leads in the table represent the companies or organizations that are providing initiatives to assist and monitor compliance with the DSCSA, while their respective pilot project is the project undertaken to do so.

TABLE 4: DSCSA PILOT PARTICIPANTS AND PROJECTS

Project Leads	Pilot Project
AmerisourceBergen/ Xavier Health	Through scanners, AmerisourceBergen/Xavier Health can implement an end-to-end process
Cardinal Health	Cardinal Health will use an EPCIS data exchange to keep track of their aggregated and serialized products
Franciscan Missionaries of Our Lady Health System (FMOLHS)	Uses EDI 856 and barcode scanning to automatically match data from the start of the product
GS1	To better connect distribution facilities by using 2D barcode scanners
IBM/KPMG/Merck/ Walmart	Implemented a cloud-based blockchain that will create an end-to-end traceability
ICON INDICES	Using Web 3.0 facilities, ICON INDICES can gather information, build a transaction history, and create a point- to-point network system
IDLogiq	Implementing 2D bar codes, NFC labels, and RFID tags, IDLogiq technology can give real-time data through the ability of blockchain
Kit Check and Sandoz	Allows end-to-end medical intelligence with several cloud-based applications
LSPedia	The incorporation of the GSI 2D data matrix barcode will allow the better collection of data and business transactions
MediLedger	Using blockchain MediLedger, was able to meet the requirements of DSCSA
Optel	Optel uses personal blockchain technology to help grow its track and trace capabilities throughout the manufacturing process
The Optimal Solution	Using blockchain and EPCIS data to help exchange data
PriMed Pharmaceuticals	Secondary wholesaler challenges during implementation of DSCSA required track and trace platforms
RFXCEL (now Antares Vision Group)	End-to-end traceability through serial software tracking using the cloud
Rymedi	Intra- and inter-healthcare systems are transferred through the blockchain systems
Sanofi	Sanofi can use a two-step process contract manufacturer and market authorization holder; through 2D barcodes Sanofi can verify the locations of products
TraceLink	By using EPCIS, the exchange of data has become more secure
UCLA Health	The blockchain used will be called BRUINchain; this blockchain will include 2D barcoding
TrackTraceRX	Implements a traceability cloud portal to access the details in every phase of the product
InfiniTrak	Uses a cloud-based, service-oriented architecture to track the present and past locations of different products
Zebra	Uses track and trace systems through Bluetooth, scanners, and a variety of other mobile computers; also uses Zebra Machine Vision to help make sure the product is correct
AbbVie	Works through a CMO to aggregate products and track them through the system
Accenture	Uses the cloud to increase the innovations of tracing data
Advasur	Uses personal Advasur 360 to help increase traceability
Be4ward Ltd	Implements blockchain to companies to help increase traceability
Blue Link ERP	Has transaction reporting (T3), the use of product identifiers, and 2D barcodes

ConsortiEX	Uses EDI to connect vendors along with 2D barcode scanning through a cloud-based system
Eli Lilly	Uses unique serialization along with a data matrix, which allows batches to be electronically linked to company servers
Eversana Life Sciences	Incorporates cloud-based technology to create an end-to-end database
Excellis Health Solutions	Use serialization and ERP strategies to enable an end-to-end database
Genentech	Creating a serialization for products and implementing blockchain technologies
Inmar, Inc.	Uses a cloud-based system to receive real-time data
LSpediA Inc	Cloud-based system to store encrypted data uses serialized data and solves data errors
Movilitas Consulting	Cloud system that incorporates SAP that can supply real-time data
Navitas	Cloud systems pharaREADY and traceREADY maintain records
OrderInsite	Cloud system that is used to track and trace solutions to help connect data to vendors

FSMA Pilot Project Program

Similar to the DSCSA Pilot Program, the FSMA Pilot Project Program is an initiative by the FDA to help standardize the regulations within the food industry. The program will also conclude regulations not only for FSMA but also produce safety rules, established through the New Era of Smarter Food Safety Blueprint. Throughout this pilot program, the FDA will monitor the resources required to review and assess third-party standards for alignment, the ability of the pilot participants to provide adequate information to enable the FDA to decide on alignment, and whether the FDA audit comparison templates are helpful in making alignment determinations. Overall, this pilot will help test the accuracy of third-party audits.

TABLE 5: COMPANIES WORKING ON FSMA

Project Leads	Pilot Project
Kiptraq	No-code apps, quick and easy access through mobile devices to make it easy to read, and traceability
BSI	Qualified individual training helps meet the FSMA requirements through risk-based learning
Kellerman Consulting	Through different plans and training, a unique process will be created to support the FSMA requirements
FoodLogiQ	Increases food transparency in the supply chain through an end-to-end cloud-based system and blockchain
Smrtr	Uses mobile services to help document vendors and simplify the process of accepting or rejecting documents
CloudHawk	Is a real-time data tracker, which uses AI firmware to help self-monitor activity
Optel	Uses personal blockchain technology to help grow its track and trace capabilities throughout the manufacturing process
Verify Technologies	Creates a system that incorporates bar codes, scanners, and food productions to simplify data entries
Safefood360	Uses a cloud-based system to generate up-to-date information
IFoodDS	Uses a cloud-based system to collect data for easy traceability
Heavy Connect	Uses a cloud-based system to have data identified in real time
Cashmere Systems	Uses a cloud-based system that allows full traceability in the distribution
Radley	Uses serial numbers to achieve real-time product traceability

Primority	Trace product throughout the manufacturing process
RFXCEL (now Antares Vision Group)	End-to-end traceability through serial software tracking using the cloud

FDA's New Era of Smarter Food Safety

The New Era of Smarter Food Safety is an initiative launched by the FDA to create a safer and more digital, traceable food system. The initiative builds on the work that the FDA has done to implement the FSMA, which established science- and risk-based protections. These goals are designed to create a safer and more digital, traceable food system. Some of the specific goals of the New Era of Smarter Food Safety include:

- Tech-enabled Traceability: Implementing new technologies to improve traceability and transparency in the food supply chain.
- Smarter Tools and Approaches for Prevention and Outbreak Response: Using new data analysis tools and predictive analytics to improve prevention and outbreak response.
- New Business Models and Retail Modernization: Adapting to new business models and modernizing traditional retail food establishments.
- Food Safety Culture: Fostering a culture of food safety across the entire food system.

Final Rule

In addition to launching individual drug and food supply chain initiatives, the FDA has also established a "Final Rule" for both supply chains. Both rules are designed to enhance traceability in the supply chain to help prevent the spread of foodborne illnesses and the distribution of counterfeit or adulterated prescription drugs. The Final Rule applicable to the DSCSA requires prescription drug wholesale distributors to verify the product identifier and other product information for certain prescription drugs before further distributing them. The rule also sets forth standards for the interoperable exchange of product tracing information between trading partners in the pharmaceutical supply chain. In contrast, the Food Traceability Final Rule under FSMA requires businesses that manufacture, process, pack, or hold certain foods to establish and maintain records containing Critical Tracking Events (CTEs) and Key Data Elements (KDEs). These businesses would be responsible for standardizing traceability record-keeping, paving the way for the industry to adopt more digital traceability systems in the future.

Verification Router Service

The Verification Router Service (VRS) is a key component of the DSCSA. It is an electronic system that enables authorized trading partners to verify the authenticity and legitimacy of prescription drugs as they move through the supply chain. The VRS is designed to provide a standardized and efficient way for trading partners to exchange information about the status of a product, including whether it has been verified as legitimate, and whether it has been the subject of a suspect or illegitimate product investigation. The VRS acts as a central hub for this information exchange, routing verification requests between trading partners and facilitating the exchange of information between them. Authorized trading partners can submit a product identifier to the VRS, which will then verify the authenticity and legitimacy of the product by checking it against a secure, centralized database. Overall, the VRS is a critical tool for ensuring the safety and security of the drug supply chain in the United States, by enabling trading partners to verify the authenticity and legitimacy of prescription drugs quickly and efficiently as they move through the supply chain.

Avery Dennison Perspective: RFID as an Enabling Solution for Both Healthcare and Food Supply Chains

What is **RFID**?

Radio Frequency Identification (RFID) stands as a groundbreaking technological innovation that revolutionizes how items are identified, tracked, and managed. At its core, RFID facilitates the wireless transfer of data to and from electronic tags, also known as RFID tags, which are securely affixed to items of interest. This wireless data exchange is achieved without the need for direct contact or visual line of sight, distinguishing RFID from traditional barcode systems. Here are some key aspects of RFID:

- Uniquely Identifies Each Item: One of the fundamental capabilities of RFID is its ability to uniquely identify each item equipped with an RFID tag. Unlike traditional barcodes, which often rely on globally standardized patterns, RFID tags boast individualized identifiers that set them apart.
- Requires a Matching RFID Reader: To engage with an RFID tag and access its embedded information, a compatible RFID reader, often referred to as an interrogator, is essential. These RFID readers emit radio frequency (RF) signals, which serve as a means of communication with the RFID tags.

How does it work?

RFID systems are composed of three essential components, working together harmoniously to enable the seamless tracking and identification of items:

- RFID Tags: At the heart of RFID technology are RFID tags, small electronic devices that are attached or embedded into items. Each RFID tag is endowed with a unique identification number, referred to as an Electronic Product Code (EPC), which is akin to a digital fingerprint for the item. This EPC serves as the key to accessing comprehensive product data stored in a secure database.
- RFID Readers: RFID readers, or interrogators, are specialized devices tasked with the role of communicating with RFID tags. These readers emit RF signals, effectively "pinging" nearby RFID tags to prompt a response. When an RFID tag receives this signal, it reciprocates by transmitting its unique EPC back to the RFID reader.
- Database: The data gleaned from RFID tags is then linked to a secure and robust database. This database acts as a central repository of information, associating each EPC with detailed item-specific data. In essence, it bridges the physical world of items with their digital representations.

RFID Tags Enable Remarkable Capabilities:

- Read Without Line of Sight: A defining feature of RFID technology is its ability to read tags without requiring a direct line of sight. This means that RFID tags can be scanned even when they are obscured or contained within packaging.
- Read Multiple Items Quickly: RFID readers are adept at rapidly scanning and identifying multiple RFID-tagged items simultaneously. Whether items are hanging on a rack or stacked on a shelf, RFID technology accelerates the identification process.
- Read Multiple Items in a Box Without Opening It: One of the most practical applications of RFID technology is its capacity to swiftly identify multiple items within sealed containers, such as boxes or crates. There is no need to physically open the container, making inventory management more efficient.



FIGURE 2: RFID Components

RFID Benefits

RFID technology is experiencing widespread adoption across a myriad of industries due to the multitude of advantages it brings to the table:

- Bridges the Physical to the Digital: RFID serves as a bridge between the physical realm of tangible items and the digital world of data. This linkage facilitates real-time tracking, traceability, and data exchange.
- Increases Accuracy: RFID significantly reduces the potential for human error associated with manual data entry or traditional barcode scanning. The precision of RFID contributes to enhanced inventory accuracy and operational efficiency.
- Automated Read: RFID technology automates the data capture process, eliminating the need for labor-intensive manual data entry. This automation streamlines processes and reduces operational costs.
- Fast Read: RFID readers can quickly and simultaneously capture data from multiple RFID tags, even in non-line-of-sight conditions. This rapid reading capability enhances efficiency across various applications.
- Uniquely Identifies Physical Items: Every RFID tag carries a unique identifier, ensuring that each item is individually distinguishable and traceable. This individualized tracking capability is particularly valuable in supply chain management and asset tracking.

Key Issues in Healthcare Where RFID Can Help:

Patient Safety Measures:

In the healthcare industry, ensuring patient safety is paramount. RFID technology plays a pivotal role in addressing several crucial aspects of patient safety:

- Full Visibility from Manufacturer to Point of Care. RFID technology provides end-to-end visibility into the healthcare supply chain, ensuring patient safety at every stage:
 - Manufacturing: Manufacturers can tag pharmaceuticals and medical devices with RFID to create a digital record of production. This ensures that products meet quality standards and have not been tampered with during manufacturing.
 - Distribution: RFID tracking allows healthcare providers to monitor the movement of products through the distribution network.
 They can verify the authenticity of products and ensure they are stored and transported under appropriate conditions.
 - Inventory Management: Hospitals and clinics can use RFID to maintain real-time inventory records. This ensures that only genuine, safe products are used in patient care.
- Automated Protection from Counterfeiting and Diversion. Counterfeit pharmaceuticals and medical products pose a significant threat to patient safety. RFID technology offers automated safeguards against counterfeiting and diversion:
 - Product Authentication: RFID tags and anti-tamper seals on product packaging provide an instant means of verifying product authenticity. Patients and healthcare providers can use RFID readers or mobile apps to confirm that a product is genuine before use.
 - Anti-Diversion Measures: RFID-enabled serialization and tracking enable healthcare organizations to detect and prevent product diversion. Any unauthorized movement of products is quickly identified, reducing the risk of counterfeit or substandard products entering the supply chain.
- Full Traceability for Recall Processes in Case of Quality Deviations. Rapid and accurate traceability is crucial in the event of quality deviations or product recalls. RFID facilitates efficient recall processes:
 - Product Recall: In the event of a quality issue or safety concern, RFID allows for swift identification and recall of affected products.
 Healthcare providers can pinpoint affected batches, minimizing patient exposure to potentially harmful products.
 - Patient Notifications: RFID data can be integrated with patient records to identify individuals who have received affected products. This enables healthcare providers to promptly notify and monitor patients for any adverse effects.
 - Root Cause Analysis: RFID's comprehensive data records can aid in root cause analysis to prevent future quality deviations.
 Identifying the source of the issue helps manufacturers and healthcare providers implement corrective actions.

Supply Chain Visibility in Healthcare:

In the realm of healthcare, achieving optimal supply chain visibility is paramount to ensuring the seamless availability of essential medical equipment, devices, and medications. RFID technology plays a pivotal role in improving supply chain visibility:

- Ensuring Medical Equipment and Devices are in Stock and at the Right Location in Time. RFID technology plays a vital role in maintaining adequate stock levels and optimizing the availability of medical equipment and devices:
 - Real-Time Inventory Tracking: RFID tags on medical equipment and devices enable real-time tracking of their location within a healthcare facility. This visibility ensures that crucial equipment is readily available when needed, reducing delays in patient care.
 - Automated Replenishment: When RFID readers detect that inventory levels are below a certain threshold, automated alerts are generated. This triggers replenishment processes, ensuring that stock is replenished promptly to prevent shortages.
 - Location Accuracy: RFID technology provides precise location information, allowing healthcare staff to quickly locate specific equipment or devices, minimizing search times and enhancing overall operational efficiency.
- Automated Restocking Checks on Medication Trays and Carts. RFID enhances medication management by automating restocking checks on medication trays and carts:
 - Smart Medication Trays: RFID-enabled medication trays can track the quantities and expiration dates of medications. As medications are dispensed, RFID readers automatically update inventory records, ensuring that trays are always stocked with the correct medications and quantities.
 - Alerts for Low Stock: When medication levels fall below a predefined threshold, RFID systems generate automatic restocking alerts. This proactive approach prevents medication shortages and ensures that healthcare providers have access to the necessary medications for patient care.
 - Enhanced Medication Safety: RFID technology reduces the risk of medication errors by verifying that the right medications are in the right trays and carts. This enhances patient safety by minimizing the possibility of administering the wrong medication.

- Less Manual Work Increases Time with Patients. RFID's automation capabilities significantly reduce manual inventory management tasks, allowing healthcare professionals to spend more time with patients:
 - Efficiency Gains: RFID eliminates the need for time-consuming manual inventory counts, data entry, and restocking checks. Staff can redirect their focus from administrative tasks to patient care activities.
 - Improved Patient Interaction: With less time spent on inventory management, healthcare providers can dedicate more attention to patient needs, improving the quality of care and patient satisfaction.
 - Reduced Human Error: Automation reduces the potential for human errors associated with manual tasks, such as counting medications or equipment. This leads to safer and more reliable patient care.

Patient Connectivity in Healthcare:

Patient connectivity through RFID technology not only fosters adherence to treatment plans but also creates a dynamic information exchange between patients and healthcare providers:

- Assisting Patient Adherence. Patient connectivity through RFID technology offers innovative solutions to enhance patient adherence to treatment plans:
 - Medication Tracking: RFID-enabled medication packaging allows healthcare providers to monitor when patients take their medications. Patients receive reminders, and RFID readers record the time and date of each dose, helping ensure adherence.
 - Customized Reminders: RFID systems can send automated reminders to patients' devices, ensuring they take medications at the right time and in the correct dosage. This personalized approach promotes adherence to treatment regimens.
 - Alerts for Missed Doses: When patients miss a dose, RFID systems generate alerts. Healthcare providers can then intervene, offering support and guidance to improve adherence.
- Providing Additional Information and Receiving Feedback. RFID-enabled patient connectivity facilitates the exchange of valuable information between patients and healthcare providers:
 - Educational Resources: Patients can access digital resources related to their conditions, medications, and treatment plans via RFIDconnected devices. This empowers patients with knowledge and promotes self-management.
 - Feedback Mechanisms: Patients can use RFID-enabled devices to provide feedback on their well-being and treatment experiences.
 This data can inform healthcare providers and lead to personalized adjustments in care plans.
 - Remote Monitoring: RFID-enabled sensors and wearables allow continuous monitoring of vital signs and health metrics. This realtime data can be shared with healthcare teams, enabling early intervention when needed.
- Ensuring Product Provenance and Authenticity Directly to the Consumer. RFID technology offers patients assurance regarding the authenticity and origin of healthcare products:
 - Product Authentication: RFID tags on pharmaceuticals and medical devices allow patients to verify the authenticity of the products they receive. Scanning the tag with a smartphone provides instant confirmation of a product's legitimacy.
 - Traceability: Patients can trace the journey of a healthcare product from its manufacturing location to their hands. RFID provides transparency regarding where a product has been and the conditions it has been exposed to.
 - Counterfeit Prevention: RFID technology acts as a powerful deterrent against counterfeit medications or medical devices. Patients can trust that the products they use are genuine and safe.

RFID Can Help Improve:

Patient Safety

- Creates visibility from manufacturer to point-of-care.
- Automates protection against counterfeit and diversion.
- Helps implement greater product quality monitoring mechanisms.

Supply Chain Visibility

- Ensures correct materials are in the right place at the right time.
- Enables automatic restocking of medications in clinical setting.
- Reduces time required by medical staff on manual processes.

Patient Connectivity

- Can potentially increase medication adherence.
- May be able to engage patients at a more significant level.
- Allows patients to track their own medications.

FIGURE 3: RFID in Healthcare: Taking a Closer Look

Key Issues in Food Supply Chain Where RFID Can Help:

RFID can provide tremendous along the food supply chain from farm or ranch to the consumer.

At the farm or ranch, RFID can:

- Increase Consumer Confidence:
 - In today's food market, consumers are increasingly concerned about the origin and safety of the products they consume. RFID technology allows farms to enhance consumer confidence by providing real-time, transparent information about their produce.
 - Farms can attach RFID tags to their products, enabling consumers to scan these tags with their smartphones. This action provides immediate access to detailed information about the product, including its origin, cultivation methods, and safety measures.
 - By offering this level of transparency, farms can build trust with consumers who value knowing where their food comes from and how it's grown.
- Improve Effective Recalls:
 - Product recalls can be a daunting challenge for farms, especially when they involve potentially contaminated or unsafe products.
 RFID technology revolutionizes the recall process.
 - Each product is tagged with a unique RFID identifier, allowing farms to track its journey through the supply chain with pinpoint accuracy. If a safety concern arises, farms can initiate recalls with incredible precision.
 - This capability significantly reduces the scope of recalls, limiting the financial impact and protecting consumers from potentially harmful products.
- Build Brand Story and Customer Connection:
 - Farms often have unique stories to tell, whether it's about their sustainable farming practices, organic methods, or generational heritage. RFID technology provides a platform to share these stories directly with consumers.
 - By scanning RFID tags, consumers can access multimedia content, such as videos, images, and narratives, that tell the farm's story.
 This connection helps consumers develop a deeper appreciation for the brand and its values.
 - Farms can also use RFID to engage customers through loyalty programs, exclusive content, and personalized offers, fostering a longterm relationship and brand loyalty.

At the processing units RFID can provide the following business benefits:

- Labor Saving:
 - o In food processing units, efficiency is crucial. RFID technology can significantly reduce the need for manual data entry and tracking.
 - RFID-enabled systems can automatically record data, such as product arrivals, processing times, and inventory levels. This automation saves time and reduces the labor required for administrative tasks.
- Less Food Waste:
 - Minimizing food waste is a top priority in the food industry. RFID plays a vital role in this effort by improving inventory

management.

- Accurate, real-time tracking of food products through RFID helps processors monitor shelf life and quality. They can identify products that are approaching expiration and take proactive steps to prevent waste.
- Margin Protection:
 - o Maintaining profit margins is challenging in the food industry. RFID assists in optimizing operations to protect these margins.
 - By automating data capture and improving inventory control, RFID helps processors avoid overproduction or stockouts, ensuring they meet demand without excess costs.
- More Effective Recalls:
 - Product recalls are a critical aspect of food safety. RFID provides processors with the ability to pinpoint the source and extent of contamination quickly.
 - In the event of a recall, processors can trace the movement of affected products throughout the supply chain, reducing the volume of products subject to recall and mitigating damage to their reputation.
- Increased Throughput:
 - RFID technology streamlines processes within processing units. Automated data capture and tracking enable faster decision-making and processing.
 - RFID also facilitates better scheduling, maintenance, and resource allocation, leading to increased throughput and higher productivity.
- Increased Traceability:
 - o Traceability is essential in ensuring food safety and quality. RFID offers precise and comprehensive traceability solutions.
 - Each product can be tagged with a unique RFID identifier, allowing processors to trace its journey from the processing unit to the end consumer. This level of traceability enhances transparency and trust.

At the distribution center, the following benefits can be achieved using RFID:

- Labor Saving:
 - o Distribution centers are hubs of activity, and RFID technology can greatly reduce manual labor requirements.
 - RFID-enabled systems streamline inventory management, shipment verification, and order processing. Staff can quickly and accurately scan items without the need for time-consuming manual entry.
- Increase Throughput (Truckloads and Pallets):
 - o Distribution centers are responsible for handling large volumes of products daily. RFID enhances throughput in multiple ways.
 - RFID readers can rapidly identify and track multiple items simultaneously. This feature expedites the loading and unloading of truckloads and pallets, reducing wait times and improving overall efficiency.
- Less Waste:
 - Reducing waste is a primary objective in the food supply chain, and distribution centers play a pivotal role in achieving this goal.
 - RFID technology optimizes inventory control and minimizes errors. This ensures that products are handled with care and that perishables are distributed promptly, reducing the risk of spoilage and waste.

The business benefits of RFID at Quick Service Restaurants (QSRs), Grocery Stores (GROCERS), and Convenience Stores (C-STOREs) can be summarized as following:

- Labor Saving:
 - In busy QSRs, grocery stores, and convenience stores, time is of the essence. RFID technology can significantly reduce the time spent on routine tasks.
 - Employees can use RFID-enabled scanners to quickly and accurately track inventory levels, manage stock replenishment, and handle checkout processes more efficiently.

- Increase Margins:
 - For businesses in the food supply chain, profit margins are a critical concern. RFID technology helps optimize operations to boost profitability.
 - Real-time inventory tracking prevents overstocking and stockouts, leading to better margin management and reduced losses due to unsold or spoiled products.
- Optimize Omni-Channel:
 - o In today's retail landscape, omni-channel operations are essential for meeting customer expectations.
 - RFID enhances inventory visibility across online and offline channels. Customers can seamlessly order products online, pick them up in-store, or have them delivered.
- Improve Consumer Experience:
 - The customer experience is paramount in QSRs, grocery stores, and convenience stores. RFID can play a significant role in enhancing this experience.
 - Quick and accurate checkouts, as well as readily available product information, lead to higher customer satisfaction.
- Reduced Food Waste:
 - \circ Food waste is a significant issue in the food supply chain, but RFID helps address it.
 - o Real-time monitoring of product expiration dates allows businesses to rotate stock efficiently, ensuring older items are sold first.
- Recall Management:
 - o In the event of a product recall, rapid identification and removal of affected items are crucial to consumer safety.
 - RFID technology facilitates precise and swift recall processes, minimizing the impact on consumers and protecting brand reputation.
- Inventory Accuracy:
 - o Maintaining accurate inventory levels is a continuous challenge in these businesses. RFID mitigates inventory discrepancies.
 - With RFID, businesses can perform inventory counts quickly and with a high degree of accuracy, reducing the risk of errors.

And lastly, RFID provides benefits at the consumer level:

- Labor Saving:
 - o RFID technology benefits consumers by making their shopping experience faster and more convenient.
 - At grocery stores and supermarkets, RFID-enabled checkout systems can quickly and accurately tally items, reducing checkout lines and wait times.
- Increase Consumer Trust:
 - o Consumers today are increasingly concerned about the safety and authenticity of the food they purchase.
 - RFID provides a means of tracking and verifying the entire journey of a product, from the farm to the store, instilling greater trust in the food supply chain.
- Brand Loyalty:
 - o Brands that embrace RFID technology to enhance transparency and traceability often gain a competitive edge.
 - Consumers are more likely to remain loyal to brands that prioritize their safety and provide detailed product information, which RFID enables.
- Authentication and Product Visibility from Farm to Fork:
 - o RFID tags on food products allow consumers to access detailed information about a product's origin, processing, and journey.
 - Scanning an RFID tag with a smartphone provides access to data like farm location, harvest date, processing methods, and more.
 This transparency reassures consumers about the product's authenticity and quality.

RFID Uses Along the Food Supply Chain

	Farm or Ranch	Food Processor	Distribution Center	Grocer/QSR/Conv. Store	Consumer
Use Case	 Traceability and authentication of production source. 	 ✓ Elimination of manual scanning. ✓ Improved inventory accuracy. ✓ Expiry date management 	 ✓ Elimination of manual scanning. ✓ Improved inventory accuracy. ✓ Expiry date management 	 ✓ Item and case level inventory scanning ✓ Expiry date management Expiry date management ✓ Frictionless checkout 	 ✓ Smart appliances ✓ Connection to brand via device (NFC) authentication
Business Benefits	 Increased Consumer Confidence More effective recalls Brand story and customer connection 	 Labor savings Increased throughput Increased trceabilty Less food waste Margin protection More effective recalls 	 Labor savings Increased throughput (truckloads and pallets) Less food waste via operational improvements (FIFO) 	 Labor savings Increased margins Omni-channel optimized Irmpvoed consumer experience Reduced food waste Improved recall mangement Better inventory accuracy 	 Increased consumer trust Greater brand loyalty Authentication and product visibility from farm-to-fork

FIGURE 4: RFID Benefits in the Food Supply Chain

RFID and Healthcare Regulations

Healthcare regulations play a crucial role in shaping RFID-based healthcare applications. RFID technology must align with these regulations to ensure patient safety, data security, and compliance with legal standards. Here are key healthcare regulations that impact RFID-based healthcare applications:

- Health Insurance Portability and Accountability Act (HIPAA): The HIPAA Security Rule mandates that healthcare providers safeguard electronically stored protected health information (ePHI) using administrative, physical, and technical safeguards. RFID applications in healthcare must adhere to these regulations to ensure the confidentiality, integrity, and security of patient data. HIPAA ensures that patient confidentiality remains intact, regardless of the technology employed, including RFID.
- Compliance Benefits: RFID technology can assist healthcare facilities in achieving compliance with DSCSA (Drug Supply Chain Security Act) regulations and HIPAA. By automating information flow and reducing manual labor, RFID improves efficiency while maintaining patient safety and data confidentiality. Healthcare personnel can dedicate more time to patient care rather than administrative tasks.

RFID and Food Regulations

RFID-based applications in the food industry are influenced by food regulations that prioritize safety, traceability, and sustainability. Here are some significant food regulations impacting RFID-based applications:

- Food Safety Modernization Act (FSMA): FSMA focuses on preventing food contamination, shifting from a reactive to a proactive approach. RFID technology can assist in tracking food from farm to table, ensuring compliance with FSMA standards. RFID enhances traceability, reduces response time to food safety incidents, and promotes safer food supply chains.
- French Act of Law Against Waste and for a Circular Economy: This law encourages businesses, including fast-food restaurants, to adopt circular practices and reduce waste. RFID can facilitate compliance with this law by enabling businesses to track and manage reusable containers. Fast-food establishments can use RFID tags to monitor the use of reusable containers, promoting sustainability.

RFID and Security

RFID technology prioritizes data security and offers several security measures to protect information. Compared to traditional technologies like barcodes, RFID provides enhanced security features, making it a preferred choice for various applications. Here's how RFID contributes to security:

- Password Protection, Locking, Encryption, and Blockchain Security: RFID systems employ these measures to secure data effectively. Unlike barcodes or printed information, which can be easily copied or read by unauthorized parties, RFID data remains highly secure. For instance, Avery Dennison Smartrac's Circus[™] Pro utilizes advanced encryption for secure product authentication.
- Counterfeit and Diversion Protection: RFID-tagged products are extremely difficult to counterfeit. By embedding RFID tags into products and using encryption, brand owners can ensure product authenticity throughout the supply chain. This technology strengthens serialization in compliance with regulations like the DSCSA. In the event of a recall, RFID enables precise identification of target items with detailed manufacturing information.

Axia's Perspective: RFID as an Enabler Solution for Both Healthcare and Food Supply Chains



Interoperability

Interoperability refers to the ability of different electronic systems, technologies, or components to seamlessly work together and exchange information.

- Interoperable electronic systems enhance tracing, but detecting counterfeits or spoiled items is crucial.
- 2D barcodes can have counterfeit product information attached, making detection difficult.
- Identical barcode information on counterfeit products is indistinguishable from genuine ones.
- Extra layers of printed information can obscure barcodes, allowing tampering.
- Standard barcodes require individual scanning, leading to slow operations, increased labor costs, and errors.
- To strengthen supply chains, new technologies should complement barcodes for robustness.

For DSCSA and FSMA to achieve their objectives, a more comprehensive solution is required to ensure counterfeit and expired products are not allowed to enter the supply chain. To solve this challenge, the industry should seek to integrate new technologies to supplement barcodes as the underpinning technology for electronic interoperable systems to make the pharmaceutical and food supply chain robust and tamperproof.



End-to-End Traceability

End-to-end (E2E) traceability refers to the ability to track and monitor a product's journey and information from its point of origin to its final destination within a supply chain. It involves capturing and recording data at every step of the product's lifecycle, allowing for complete visibility into its movement, handling, and transformation.

- E2E traceable value chain offers safety, quality, and authenticity benefits.
- It reduces diversion and counterfeiting, enhances profitability, and minimizes shortages.
- It includes real-time monitoring of product movement within the supply chain.
- E2E traceability detects diversions, enables interception, and eliminates counterfeits.
- It allows detection of non-manufacturer products, incorrect entry, or reentry into the supply chain.

- Alerts are triggered for tampered or compromised products, preventing patient harm.
- Dispensers can trace products back to the manufacturer, ensuring authenticity.
- Emerging technologies like Internet of Packaging (IoP) offer visibility and traceability solutions.



RFID Benefits to Improve Interoperability and End-to-End Traceability in Healthcare and Food Supply Chain

By incorporating RFID technology, interoperability is enhanced through standardized communication, automated processes, and efficient data exchange, while end-to-end traceability benefits from real-time tracking, anti-counterfeiting measures, and improved data accuracy.

- Multi-Read Capability: RFID technology allows multiple products to be read simultaneously, enhancing operational efficiency and speed.
- Automated Data Capture: RFID eliminates manual barcode scanning, reducing human errors and increasing accuracy in data collection.
- Standardization: RFID tags adhere to standardized protocols, ensuring compatibility and seamless communication across different systems.
- Real-Time Tracking: RFID provides continuous and real-time monitoring of product movement, enabling precise tracking from source to destination.
- Tamper-Proof: RFID creates a tamper-proof mechanism for tracking products, making it difficult for counterfeit items to enter the supply chain unnoticed.
- Anti-Counterfeiting: RFID's unique identification for each item enhances authenticity verification and prevents counterfeiting.
- Granular Data: RFID captures detailed information about each product's journey, allowing for comprehensive traceability and transparency.
- Enhanced Visibility: RFID offers better visibility into supply chain processes, enabling quick detection and response to any deviations or anomalies.
- Cloud Integration: RFID data can be seamlessly integrated into cloud-based systems, facilitating data sharing and enabling access across the supply chain.



FIGURE 5: RFID Application in Providing End-to-End Traceability Across the Healthcare (Left) and Food Supply Chain (Right)

Overall, RFID technology can be applied to both healthcare and food supply chain. RFID improves DSCSA and FSMA compliance by enhancing product authentication, traceability, monitoring, and data accuracy, leading to safer and more transparent supply chains for both pharmaceuticals and food products.

Conclusion

Beginning with the introduction of the DQSA and extending to the FSMA, traceability has grown in importance over the last decade. Whether ensuring that medications being administered to keep people healthy have not been counterfeited or mitigating the risk of foodborne diseases contaminating our food supply chain, visibility systems are necessary in these critical areas. While regulation has driven the need for traceability, consumers are increasingly interested in verifying for themselves that their medications are authentic and that the food they are eating is indeed healthy.

RFID has emerged as a technology capable of securely facilitating traceability and has inadvertently emerged as an extremely efficient way to track goods, especially with the tightening of labor markets. Because RFID tags can be read at a distance using RFID readers and do not have to be scanned by hand like traditional barcodes, they are becoming a more cost-effective way of ensuring compliance with these important new directives. Importantly, as RFID has gained acceptance with industry, additional use cases for the technology have been identified which will only help accelerate adoption and further reduce implementation costs in the future. Both Avery Dennison and the Axia Institute are spearheading multiple initiatives to advance the adoption and integration of RFID technology. These endeavors are geared toward enhancing supply chain traceability, in alignment with the Drug Supply Chain Security Act (DSCSA) and the Food Safety Modernization Act (FSMA) with the goal of further demonstrating the viability of this important technology.

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Avery Dennison

Avery Dennison Corporation (NYSE: AVY) is a global materials science and digital identification solutions company that provides branding and information labeling solutions, including pressure-sensitive materials, radio-frequency identification (RFID) inlays and tags, and a variety of converted products and solutions. The company designs and manufactures a wide range of labeling and functional materials that enhance branded packaging, carry or display information that connects the physical and the digital, and improve customers' product performance. The company serves an array of industries worldwide, including home and personal care, apparel, e-commerce, logistics, food and grocery, pharmaceuticals and automotive. The company employs approximately 36,000 employees in more than 50 countries. Reported sales in 2022 were \$9.0 billion. Learn more at www.averydennison.com.

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