FDA DSCSA

Blockchain Interoperability Pilot

Project Report

February, 2020

IBM KPMG MERCK Walmart

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Executive Summary (Page 1 of 2)

With almost half of the United States population taking prescription medications for various ailments and medical conditions[1]; an increase in the number of aging Americans projected to nearly double from 52 million in 2018 to 95 million by 2060[2]; and adoption of new federal laws[3], there is a significant opportunity and need to enhance transparency and trust in an increasingly complex pharmaceutical supply chain[4].

With these factors as a backdrop, the Drug Supply Chain Security Act (DSCSA) was signed into law in 2013, with the intention to allow the pharmaceutical trading partners to collaborate on improving patient safety. The law outlines critical steps to build an electronic, interoperable system by November 27, 2023, where members of the pharmaceutical supply chain are required to verify, track and trace prescription drugs as they are distributed in the United States.

Various organizations and government entities collaborate to ensure medications are safe, efficacious and are produced using the highest quality ingredients. This requires continuously evaluating and pursuing enhanced manufacturing, distribution, regulatory, and technological approaches to bring forward innovative solutions. Using iterative processes, the integrity of the supply chain can be improved by rapid identification and elimination of counterfeit medication, isolation of substandard ingredients and preventing product diversion and entry from gray markets.[5]

The need to explore new solutions prompted IBM, KPMG, Merck and Walmart to propose a blockchain solution as a response to the FDA Pilot program to examine the use of this technology in verifying and tracking pharmaceutical products in preparation for future DSCSA requirements. The four organizations believe that blockchain technology with its shareable ledger, immutable data, and inherent ability to track drug provenance, is uniquely qualified to address the various challenges of the pharmaceutical supply chain. The business community understands that digital transformation of this nature requires experimentation and continuous iteration as the technologies mature and evolve.

The Pilot was designed to allow for rapid alerts between supply chain partners if a medication recall were to occur, with granular identification of the impacted lot. Today, this notification process is highly manual and fragmented using various disparate systems, and thereby increasing the response time and number of patients impacted by the recall. The specificity enabled by marking serialized product in addition to using blockchain technology to quickly identify location of recalled lots and notify relevant supply chain partners, eliminates unnecessary communication and prevents valid product from being quarantined resulting in less pharmaceutical waste.

To assess if blockchain would be a suitable technology to address the needs of the pharmaceutical supply chain, the Pilot team proposed two objectives:

- Demonstrate that blockchain can provide a common record of product movement by connecting disparate systems and organizations to meet DSCSA 2023 interoperability requirements in a secure way
- Improve patient safety by triggering product alerts and increasing visibility to relevant supply chain partners in the event of a product investigation or recall

The Pilot was successful in demonstrating both stated objectives.

References:

1 https://www.cdc.gov/nchs/products/databriefs/db334.htm

2 https://www.prb.org/aging-unitedstates-fact-sheet/

3 https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf#page=13

4 http://www.americanhealthpolicy.org/Content/documents/resources/December%202015_AHPI%20Study_Understanding_the_Pharma_Black_Box.pdf

5 https://www.ncbi.nlm.nih.gov/pubmed/27354753

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Regarding the first objective of connecting disparate systems, the Pilot successfully integrated an enterprise system from a manufacturer to post serialization product data to a private permissioned blockchain and recorded subsequent actions from manufacturer, distributor and dispenser to create a common view of product movement. This allowed the second objective of transparency to be achieved, by enabling a querying functionality of the blockchain to verify serialized product data of the medication prior to being dispensed.

Solving for an interoperable solution that will track and trace pharmaceutical products between trading partners will require a fundamental consideration for governance. To foster industry adoption, an egalitarian, inclusive, open-sourced commercial solution should be considered to help launch a blockchain network intended for information exchange of the pharmaceutical product transactions in the United States. Uniting the industry around this concept is a formidable challenge, but one which can be solved by a collaborative approach. Given the broad adoption of a select number of technical solutions – each adhering to a common standard – that have been deployed to achieve compliance to date, the integration challenge of interoperability can be accelerated.

Leveraging blockchain technology, trading partners can also look to solve various challenges faced by the pharmaceutical supply chain while meeting regulatory compliance with DSCSA and allow adopting organizations of this technology to improve patient safety though timely communication and interventions.

IBM, KPMG, Merck and Walmart agree that our Pilot program was successful in addressing the stated objectives and collectively believe there are benefits to using blockchain both for, and beyond, DSCSA compliance.

Overview (Page 1 of 3)

On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113-54) was signed into U.S. law, which outlines critical steps to build an electronic interoperable system by November 27, 2023, where members of the pharmaceutical supply chain are required to verify, track and trace prescription drugs as they are distributed within the United States. Considering the magnitude of technology and system upgrades, adoption of new processes and change management required to implement an interoperable system, a phased approach was prescribed for employing the DSCSA requirements. The legislation is intended to help protect patients from exposure to drugs that may be counterfeit, stolen, contaminated or otherwise harmful, and improve the detection and removal of potentially dangerous drugs from the pharmaceutical supply chain.

In March 2019, industry leaders Merck and Walmart collaborated with IBM and KPMG to participate in the Pilot Project Program under the DSCSA section 582(j) of the FD&C Act to shape and define interoperability between trading partners and demonstrate how a novel technology, such as blockchain, can be used to solve for DSCSA interoperability requirements. This report contains key findings and lessons learned in developing a blockchain-enabled solution to evaluate if the technology is a viable solution to demonstrate compliance with DSCSA 2023 requirements of interoperability. Moreover, the Pilot project team explored a use case of value beyond compliance to demonstrate business value of enhancing the medication recall process.

Participant	Role
IBM	Solution Provider
KPMG	Solution Provider and Subject Matter Expert
Merck	Manufacturer
Walmart	Dispenser

Table 1: Organizations in the Pilot team

For more information on DSCSA and pharmaceutical product serialization, please see “Serialization and DSCSA Background” in the Appendix.

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Blockchain Benefits

Blockchain is a distributed ledger technology that provides an immutable audit trail of transactions, allowing for transparency while maintaining data privacy, and uniting disparate sources of data from various stakeholders. Immutability of the data enables the technology to be considered for highly regulated industries such as healthcare. Another potential benefit that drives value is the capability of this technology to enable reconciliation in real time by confirming transactions without seeing the underlying data. This technology also has the potential to reduce costs, automate and eliminate manual processes and introduce a transparent supply chain among trading partners.

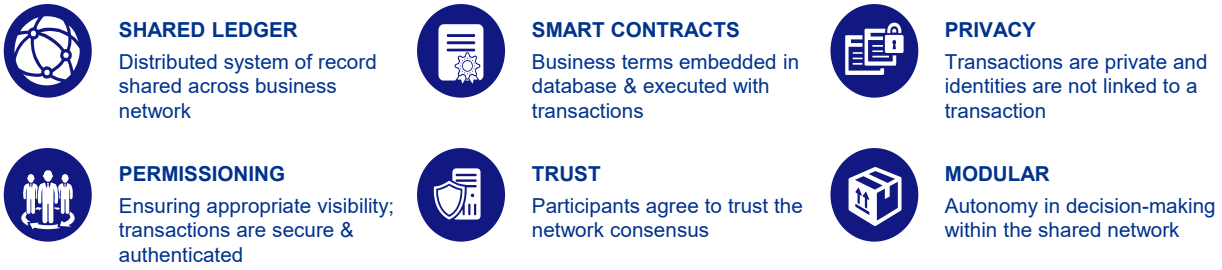


Figure 1: Summary of potential benefits associated with leveraging blockchain technology.

For the pharmaceutical supply chain, this technology has the potential to enable a common, shared solution where manufacturers, distributors and dispensers can work together to solve key industry challenges and collectively set the stage for common standards and procedures to address DSCSA requirements. Establishing common technical standards for a blockchain solution enables interoperability and enhanced visibility for all supply chain participants, regardless of their involvement in the initial blockchain development process. With the use of a blockchain-enabled solution, this technology might be able to address the foundational requirement of track and trace for DSCSA in addition to establishing trust between trading partners.

For more information on the benefits of blockchain, including smart contracts and off-chain data storage, please see “Blockchain Benefits Expanded” in the Appendix.

Overview (Page 3 of 3)

Solution Overview

The final DSCSA milestone requires the use of physical product identifiers and corresponding electronic records to track and trace the ownership of prescription drugs units between supply chain participants using an electronic, interoperable system. This is a great challenge for the industry, as the pharmaceutical supply chain consists of a complex network of participants with various levels of interactions, ownership and accountability with limited or no visibility of end-to-end product movement from manufacturing to the point of dispense.

The goal of this Pilot project was to create a blockchain solution that could support each participant's ability to comply with regulatory requirements in a trusted, secure way while fulfilling the needs of the pharmaceutical supply chain by maintaining data privacy and creating a permissioned view of product movement.

Key objectives for the Pilot team:

- Demonstrate that blockchain can provide a common record of product movement by connecting disparate systems and organizations to meet DSCSA 2023 interoperability requirements in a secure way
- Trigger product alerts and increase visibility to relevant supply chain partners in the event of a product investigation or recall in support of patient safety

The application was developed to demonstrate the following anticipated benefits of a blockchain-enabled solution:

- Enable interoperability between supply chain partners in an immutable, distributed ledger
- Provide a single, shared source of truth associated with pharmaceutical product movement
- Illuminate sources of suspect or illegitimate activity
- Improve patient safety in the event of a product recall

The Pilot team also sought to increase practical learning and experience with interoperability among existing pharmaceutical trading partners, establish a deeper understanding of the required process-level interactions across supply chain stakeholders, and identify opportunities to develop solutions that will further improve pharmaceutical supply chain security.

For more information on the solution overview, please see "Solution Architecture" in the Appendix.

Results and Discussion (Page 1 of 3)

Test Results

Upon conclusion of the technical development, the solution was tested by the Pilot participants where defined test scenarios associated with the objectives were executed to synthesize final results. The Pilot team focused on evaluating the applicability of blockchain technology and identifying challenges associated with interoperability among stakeholders.

The Pilot participants noted the following observations during testing:

Drug provenance and data privacy

- Demonstrated that drug's provenance is accurately captured on the blockchain through recording shipment, receive and dispense actions against serialized product data to create a continuous link of product movement
- Demonstrated that data privacy can be maintained among network participants with limited one up, one down permissioned view

Increased patient safety

- Demonstrated that product alerts for investigation and recalls can quickly be sent to and received by network participants, who have or have previously possessed the impacted product (s)
- Demonstrated that network participants can quickly identify products subject to an alert that are or have been in their possession though the product security UI of the solution
- Demonstrated that products cannot be dispensed more than once – reducing the potential of dispensing counterfeit product by sequencing actions associated with product movement for each GTIN
- Demonstrated ability to restrict shipping, receiving or dispensing of product that is subject to an alert for investigation or recall by changing the product status to non-saleable

Reporting

- Demonstrated a method for each network participants to retrieve drug provenance information related to recalled product to support timely control of impacted product

Recall functionality

The Pilot provided enhanced recall functionality to accelerate the communication process related to alerting downstream partners with affected inventory. The current process of drug recalls is expensive and time-consuming, with a lack of standardized processes and alert mechanism between trading partners. In the event of a recall, companies must rely on collaborating to quickly identify recalled product and communicate to downstream partners with the impacted product lot. Currently, due to the lack of interoperability and visibility to lot-level information, it can take up to 3 days to identify impacted product and alert downstream partners with this information. It was demonstrated in the Pilot that using blockchain technology, the process would be exponentially expedited. Using blockchain technology, partners may be alerted in as little as ten seconds.*

For more information on the testing approach and results, please see "Solution Testing" in the Appendix.

**Time estimation due to lack of integration of Pilot with existing legacy systems of the Pilot participants.*

Results and Discussion (Page 2 of 3)

Blockchain Evaluation and Governance

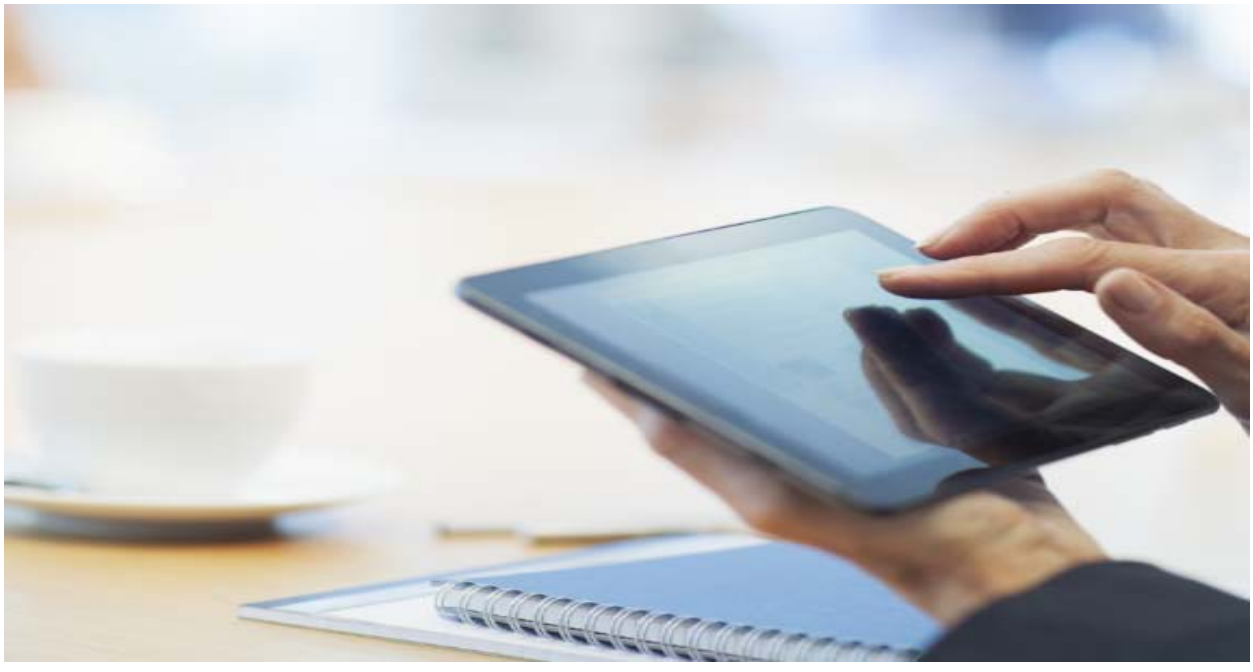
The Pilot demonstrated that blockchain technology offers a decentralized, trusted way to share information across networks participants, providing a path to comply with DSCSA 2023 interoperability requirements. The Pilot also demonstrated minimal complexity associated with the integration of stakeholders' existing operational systems used in packaging and distribution, which translates to reducing the individual burden of achieving interoperability.

Blockchain is an advanced technology requiring industry participation, with potential to advance interactions in the pharmaceutical supply chain. Pursuing a blockchain-based solution can enable DSCSA compliance while enabling new business models.

The complexity of moving towards a blockchain solution is in building consensus for governance models. The Pilot team believes that it is only possible to adopt blockchain as an underpinning technology if an equitable governance model is established with no single establishment gaining an undue advantage from controlling the blockchain network. Therefore, it is important to develop a defined industry governance framework associated with the blockchain network itself as well as data standards for information exchange such as GS1, integration requirements and solution triggers.

An inherent benefit of blockchain is that it enables trust in a decentralized manner – trust is established by the network itself and the network participants, and not by a single or third party. Since the network is governed by industry participants and not a single party, the network members can collectively establish standards which the network then executes and operates by.

Alternatives to blockchain could create a centralized entity that would manage actions and ensures consistency across the network. This means there will be fragmentation and data sharing challenges because a single entity with the ability to establish truth would become incredibly powerful.



Results and Discussion (Page 3 of 3)

Value Beyond Compliance

The pharmaceutical supply chain has recognized there might be additional business value associated with introducing product traceability across the pharmaceutical supply chain. With a digital record following the product movement, new opportunities to solve key challenges can be explored to transform how the industry operates today. Some examples of new opportunities include cold chain logistics with IoT sensors, addressing drug shortages and streamlining processes to introduce a lean supply chain with optimized inventory management. This Pilot solution can be further extended to address these issues in future iterations by addition of data, and participants and by incorporating new functionalities to the backbone of product movement and exchange of serialized product data needed for DSCSA compliance.

Future Considerations and Enhancements

Throughout the project's duration, the Pilot team identified several future enhancements for consideration. The approach for this first iteration was to solve for a subset of the regulatory requirements with a limited number of participants to ensure the baseline functionalities related to blockchain would be addressed and tested. For future enhancements, the team would like to expand the solution with more users and products tested and include more complex supply chain scenarios such as reverse distribution and returns. It is also important to define a proposed deployment model and assess speed and scalability of the solution to ensure it fits the industry needs of supporting a high number of transactions per second. The team recognizes the importance of solving for operational inefficiencies by further assessing internal business processes and integrating action triggers and data flow with existing systems used by manufacturers, distributors and dispensers.

Scenarios out of scope for the Pilot to be addressed in future enhancements include:

- Authorized trading partner licensing
- Aggregation, disaggregation and related inference
- Product divestitures
- Removal of quality samples during distribution
- Reverse distribution
- Product return

Some of the broader questions related to DSCSA 2023 compliance require discussion at the industry-wide level with an understanding of FDA/regulator experience in the future. As different blockchain solutions are being developed and tested to support DSCSA compliance, interoperability between various blockchains would also need to be addressed and tested.

Appendix

Acknowledgements (Page 1 of 1)

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Table 2: List of contributors in the Pilot project

Definitions (Page 1 of 1)

Term/Acronym	Definition
AI	Application Identifier: A field (typically two digits) at the beginning of a data string that uniquely defines the meaning and the format of the data that follows.
Aggregation	The electronic linkage of "child" serial numbers to a "parent" serial number (e.g. unit serial numbers linked to case serial number, case serial numbers linked to pallet serial number), which is used for efficient assignment of serial numbers.
API	Application Program Interface: a set of routines, protocols, and tools for building software applications and integrating disparate software systems.
Data Matrix	A standalone, two-dimensional matrix symbology that is made up of square modules arranged within a perimeter finder pattern. Data Matrix symbols are read by two-dimensional imaging scanners or vision systems.
Dispenser	An entity in the Pharmaceutical Supply Chain, also referred to as a Pharmacy, which is authorized by law to dispense or administer prescription drugs.
DSCSA	Drug Supply Chain Security Act
DQSA	Drug Quality and Security Act
EPCIS	Electronic Product Code Information Services: GS1 data set for sharing event data between trading partners.
FDA	Food and Drug Administration
GLN	Global Location Number: GS1 data set that uniquely identifies location and business entities.
GS1	The global standards organization that defines standards including GTIN, SSCC, GLN, and EPCIS.
GTIN	Global Trade Item Number: GS1 data set that uniquely identifies trade items.
GxP	Good (x) Practices: Guidelines established in the U.S. by the Food and Drug Administration.
HIPAA	Health Insurance Portability and Accountability Act
IFT	IBM Food Trust™ (IFT), built on blockchain, is a software-as-a-service (SaaS) solution which enables product traceability across the supply chain ecosystem.
IoT	Internet of Things: a system of interrelated computing devices, machines and objects that are provided with unique identifiers, and are enabled to transfer data over a network.
NDC	National Drug Code: number used to identify drug products.
Pharmaceutical Manufacturer	An entity in the Pharmaceutical Supply Chain also referred to as the Market Authorization Holder (MAH), who is authorized to manufacture a prescription product.
Pharmaceutical Supply Chain	Various entities that operate in the pharmaceutical ecosystem ranging from Manufactures, Distributors, 3rd Party-Logistics Providers, and Dispensers (pharmacies).
TI	Transaction Information
Wholesale Distributor	An entity in the Pharmaceutical Supply Chain that purchase product from the manufacturer and distributes the product to dispensers.
XML handler	Java component that writes an outbound integration message into a file in XML format that conforms to GS1 standards.

Table 3: Terms and acronyms used in the report

Serialization and DSCSA Background (Page 1 of 2)

Serialization is the process of applying unique identifiers to a pharmaceutical package that can be tracked as it moves through the supply chain. There are serialization requirements in over 40 countries where specific requirements vary per market, but in nearly every serialization mandate, there are at least two types of requirements that need to be specified and implemented: 1) encoding and printing of serial numbers and 2) a verification system.

Drug Quality and Security Act (DQSA) includes two different laws: The Compounding Quality Act and the Drug Supply Chain Security Act (DSCSA). DSCSA governs the pharmaceutical serialization requirements to increase traceability of medications in the U.S. market and aims to protect consumers by eliminating counterfeit drugs and identify product diversion.

Counterfeit drugs have a significant cost impact on the pharmaceutical supply chain, leading not only to patient risk and safety concerns, but also brand damage and undermine consumer trust. Compared to other markets, the United States currently has a low level of counterfeit pharmaceuticals in circulation, but with the increase of global delivery of products from countries where counterfeit pharmaceuticals are more prevalent, the need for a secure supply chain is becoming more important to address and is expected to be more challenging to manage in the future. The total value of the counterfeit pharmaceutical market globally has been estimated to be $200 billion dollars where approximately 80% of counterfeit medication in the United States is originating from overseas manufacturing.[6]

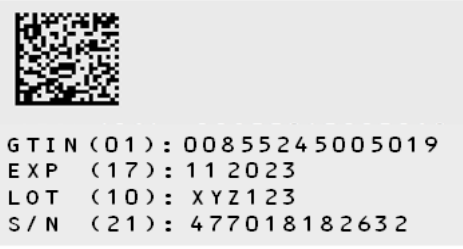


Figure 2: The pharmaceutical pack is marked with a barcode encoded with the serial number (AI: 01), Global Trade Item Number (GTIN, AI: 21)), lot (AI: 10) and expiry date (AI: 17).

To address this, the DSCSA was signed on November 27th 2013 with a 10-year implementation timeline. Title II of DQSA, the DSCSA, outlines steps for the pharmaceutical supply chain to establish an electronic, interoperable system to identity and trace prescription drugs from the point of manufacturing to dispenser receipt.

Currently, pharmaceutical manufacturers, the market authorization holder (MAH), are required to encode unique serial numbers and other relevant data associated with the product (Global Trade Item number – GTIN or National Drug Code - NDC, lot number, and expiration date) on saleable units and homogenous cases supplied to the market. In addition, manufacturers must have systems in place to verify serial numbers and validate transaction history in support of an investigation. Today, the encoded data are contained in a corresponding electronic record used for verification requests and are currently hosted in the manufacturer's internal systems. In the future, the serialization data needs to be shared with trading partners as the product moves throughout the supply chain among distributors, 3PLs, re-packagers and dispensers.

Reference:

6 https://healthresearchfunding.org/20-shocking-counterfeit-drugs-statistics/

Serialization and DSCSA Background (Page 2 of 2)

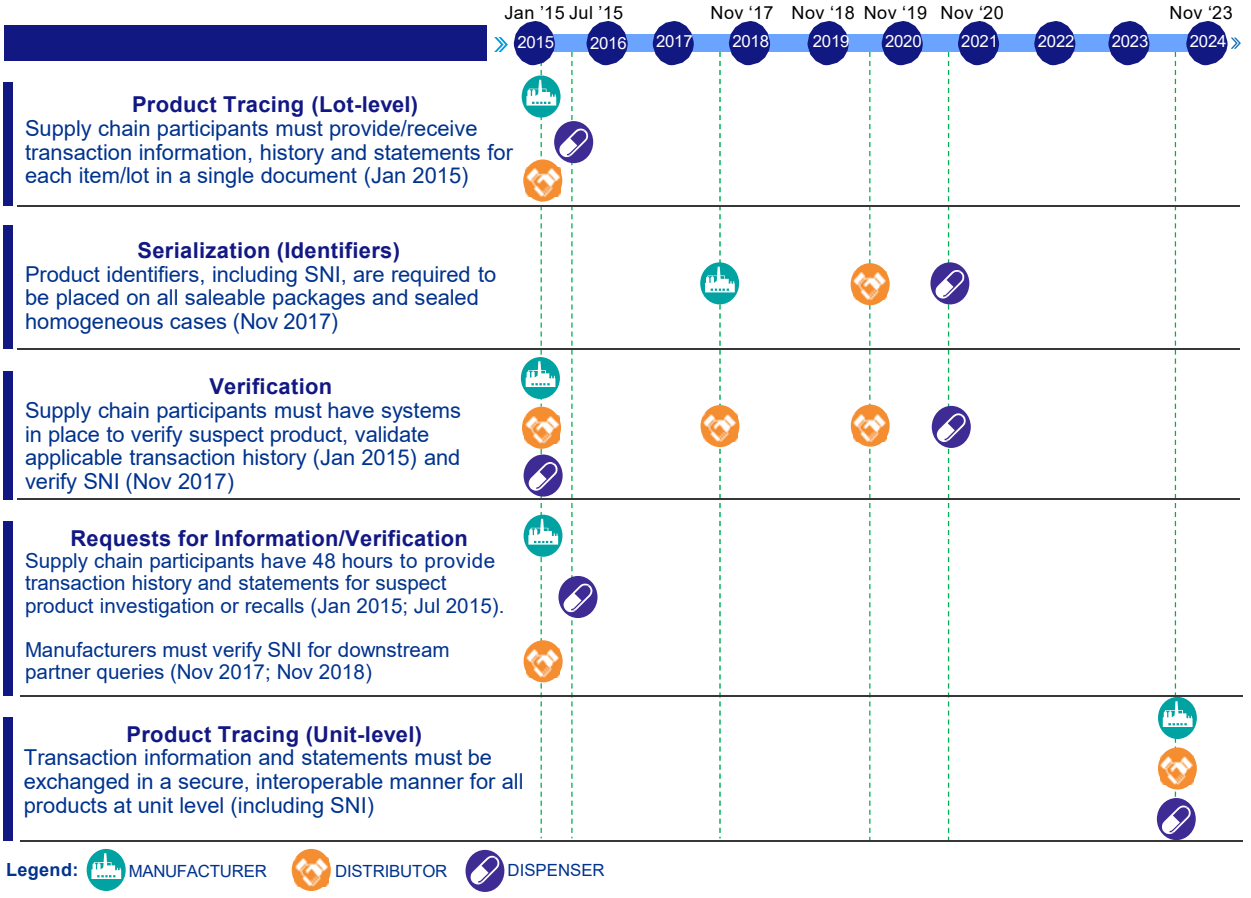


Figure 3: U.S. DSCSA summary overview of phased requirements related to product labeling (serialization) and data exchange.

DSCSA Industry Challenges (Page 1 of 1)

The final milestone of DSCSA compliance for 2023 is a challenge for the industry to implement as it requires interoperability and exchange of transaction information at the unit-level in a safe, secure manner. Today, the pharmaceutical supply chain is comprised of manufacturers, re-packagers, distributors, dispensers and 3PLs who traditionally have had limited or no visibility of product movement beyond direct trading partner interaction.

The volume of data and transaction speed needed to support several ownership changes for each saleable unit is also a concern for the industry, since the expected annual transaction volume to support interoperability may exceed 15 billion records.

The DSCSA requires that trading partners deploy systems to exchange transaction information as well as investigate and respond to FDA inquiries in support of suspect/illegitimate product investigation. However, without a centralized host of systems for trading partners to use in support of verification and serialized interoperability, the industry must take an active part and collectively come together to evaluate solutions that fit their needs while complying with the law.

Blockchain Benefits Expanded (Page 1 of 1)

Through the use of smart contracts and off-chain data, blockchain is capable of working with large amounts of data and enables scalability across multiple dimensions: participants, transaction volume, and product type. Smart contracts, or chain code, are digital representations of business-driven contracts that reside on the blockchain. Smart contracts define the relationship between two or more parties and can enable automation of business processes among network members which can eliminate operational inefficiencies by automation and provide greater accuracy. For example, in future iterations of the Pilot, a smart contract could enable automatic product re-ordering in the event that a product is damaged in transit or enable payment to be released from sender to recipient upon verified receipt of product.

A blockchain network purposefully may be designed to maximize the benefit of off-chain storage. For example, a blockchain network may utilize off-chain storage to store personal identifier information to facilitate compliance with HIPAA or used to facilitate the sharing of large files or documents. In addition, off-chain storage may be considered in order to maximize search query efficiency. However, network designers must ensure that the search capabilities enabled by the off-chain database adhere to the network's existing permission structure.

The cryptography innate to blockchain enables an immutable and verifiable chain of custody that can be used to support product investigation. Participants also have the ability to independently verify products without the need to contact the manufacturer or any other trading partners.

Additionally, by combining blockchain with other technologies such as internet of things sensors (IoT) or ultra-high-resolution cameras, network stakeholders could establish a digital twin of a physical product on blockchain. The digital twin could be leveraged to represent an immutable record of product geolocation or temperature data and could also increase patient safety by ensuring that the product label has not been copied.

Solution Approach and Design (Page 1 of 1)

The participants started the project by mapping out the pharmaceutical supply chain processes to identify pain points and potential areas of opportunity related to DSCSA within the current ecosystem. Next, the team outlined a vision for enhancing patient safety by improving supply chain visibility and by automating the distribution of product alerts across relevant network stakeholders in the event of an investigation of serialized products.

The participants then identified key stakeholder personas that could benefit from using the envisioned solution. These stakeholder types were further defined as network participant and user personas - their needs, pain points, and behaviors respective to operational efficiency and current and future compliance with the DSCSA were documented to develop an initial set of proposed functional and technical requirements.

The Pilot was designed and developed in an iterative manner using agile methodology. From this set of requirements, the team created initial user stories – descriptions of features and functionalities that are used to effectively prioritize, scope, and build the desired solution. Once the user stories were prioritized and the Pilot was officially scoped, the team conducted iterative cycles (sprints) of design and development, continuously integrating new learnings, requirements, and feedback to strategically plan, implement, and refine the solution architecture and the user experience (UX) across the identified web application user interfaces (UIs).

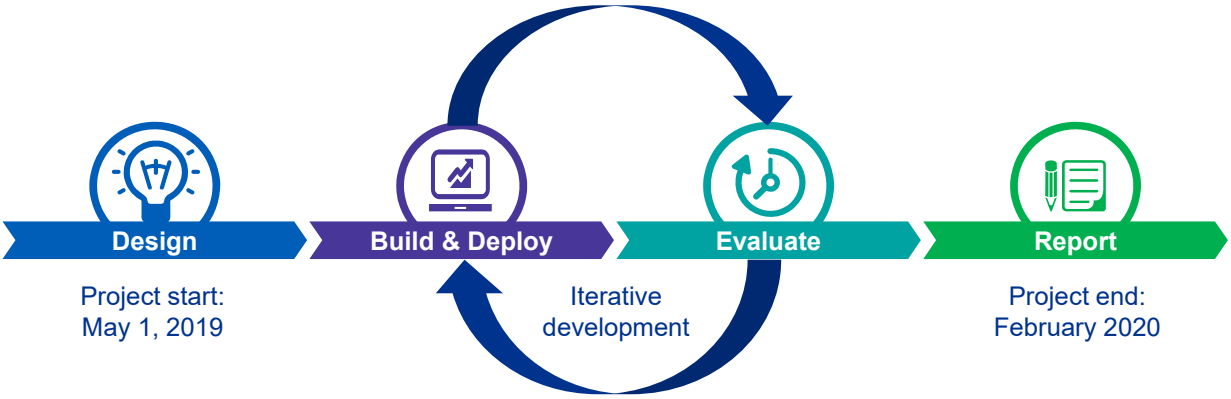


Figure 4: The Pilot team leveraged an iterative approach and, using accelerators, developed the blockchain platform in less than 6 months.

Key solution functionalities

- **Track and Trace**: Track and trace a drug at the unit level from the point of commissioning to the point of dispense
- **Verify**: Complete verification requests to inquire about a drug's validity
- **Recall**: Rapidly retrieve all relevant information about a given pharmaceutical lot in the event of a manufacturer-generated recall
- **Alert**: Transmit alerts throughout the network about drugs that have been flagged as under evaluation, under investigation or recalled status, to prevent the products from further shipment or dispense

Functional Requirements (Page 1 of 5)

The requirements related to key solution functionalities outlined above are explained in detail below.

Track and Trace: Track and trace a drug at the unit level from the point of commissioning to the point of dispense

The system should be able to track and trace and exchange serialized data upon changing ownership between trading partners.

1.0: Execute EPCIS messages associated with product distribution	• Import commissioning file from SAP ATTP (Merck's system) • Only manufacturer may commission serialized units • Ship, receive and dispense product executed via Event Actions User Interface • Control sequence of events to ensure it follows: commission, ship, receive, ship, receive, dispense
1.1: Prevent an action from being executed more than once	• An action cannot be executed by the same user against the same unit/lot more than once • Manufacturer cannot ship more than once • Distributor cannot receive more than once • Distributor cannot ship more than once • Dispenser cannot receive more than once • Dispenser cannot dispense more than once
1.2: View the drug provenance from manufacturing to dispense	• Limit visibility to one up, one down of each direct trading partner interaction • View trace details: date and time of EPCIS event, product, source organization, destination organization • Manual search by serial number or lot number

Assumptions:

- Partial product dispense is out of scope

Verify: Complete verification requests to inquire about a drug's validity

The system should support verification requests of serialized units.

2.0: Verify serialized data by sending a request for verification to the blockchain	• Request must include product's GTIN, serial number, lot number and expiration date • Request may be sent using manual entry of serialized data or by using a barcode scanner for 2D Data Matrix and decoding of application identifiers to obtain serialized data
2.1: Verification response message	• If there is a match and there are no alerts associated with the product, the system should return a product status of saleable • If there is a match and the product is subject to an alert, the system should return the product's most recent alert status
2.2: Users authorized to verify product	• Only registered network participants may verify a product

Functional Requirements (Page 2 of 5)

Recalls: Rapidly retrieve all relevant information about a given product lot in the event of a manufacturer-generated recall

The system should quickly alert all trading partners with inventory subject to recalls and provide transaction history to support investigation.

3.1: Recall flag alert	• Manufacturer should be able to trigger a recall alert • Recall alerts are executed at the lot level • Once a product is recalled, further distribution and dispense should be prevented
3.2: Recall reporting functionality	• Provide ability to export transaction history after the recall has been alerted in the system

Alerts: Transmit alerts throughout the network about drugs that have been flagged as under evaluation, under investigation or recalled, to prevent the products from further shipment or dispense

The Pilot should enable users to flag products and send/receive product alerts.

4.1: Product flags	• Flag product as “Under Evaluation”, “Under Investigation,” or “Recalled” • Reverse flag from “Under Evaluation” or “Under Investigation” to “Saleable”
4.2: Product alerts	• View recent product alerts relevant to user’s organization
4.3: General permissions (details broken down in subsequent section)	• Any user who changes a product status to “Under Evaluation”, “Under Investigation” or “Recalled” has already undertaken the necessary internal steps to ensure status must be updated

Assumptions:

- Any investigation of “Under Evaluation”, “Under Investigation” or “Recalled” products will take place outside of the blockchain solution

Functional Requirements (Page 3 of 5)

Permissions

Depending on a user's role and permissions, a user should be able to trigger one of more of the following alert types

Alert	Description	Process
Under Evaluation	Internal assessment is occurring within an organization to determine if an investigation involving network members who have taken possession of the product is required.	• An alert is triggered for individual units via the Product Security UI • Stops product shipment and dispense • Provides early warning sign that a product may require investigation by broadcasting to network members who have taken possession of the product • "Under Evaluation" status can be reversed to "Saleable" to allow for further distribution per business rules
Under Investigation	Network members that have taken possession of the product have initiated a cross-party investigation.	• An alert is triggered for individual units via the Product Security UI • Stops product shipment and dispense • "Under Investigation" status can be reversed to "Saleable" by the product's manufacturer
Recalled	Investigation is complete and the manufacturer requires a recall	• An alert is triggered for the product and its lot via the Product Security UI • Stops product shipment and dispense • The product and product lot's "Recalled" status cannot be reversed to "Saleable"

Table 4: Alert types and associated processes included in the solution design.

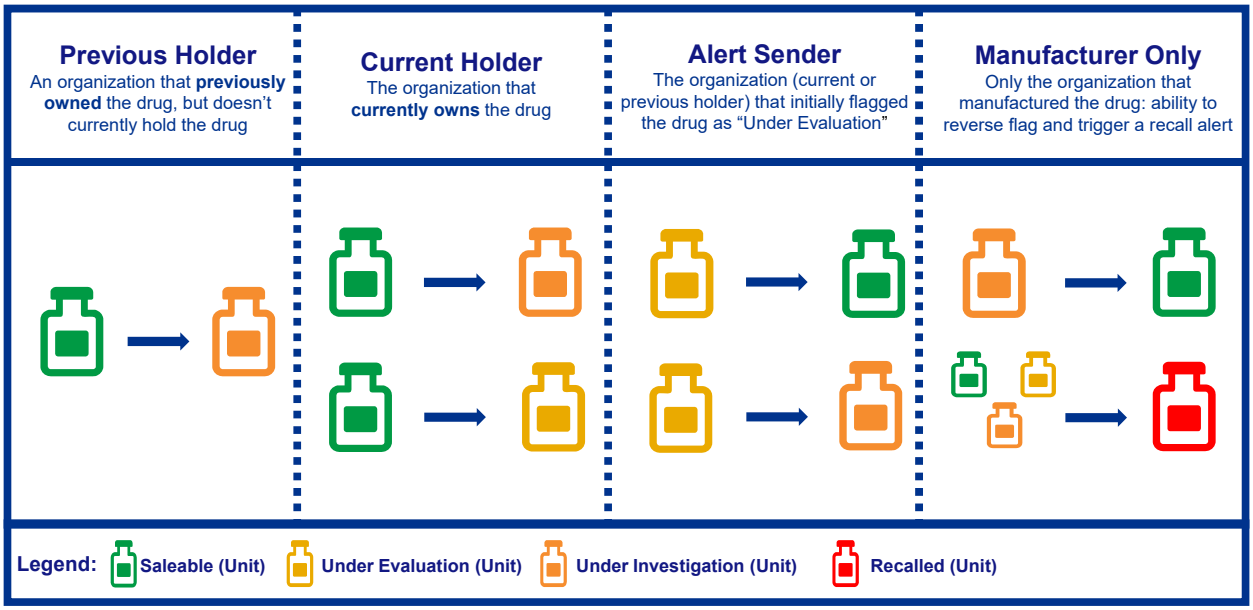


Figure 5: Possible progression of product alert statuses.

Functional Requirements (Page 4 of 5)

User Personas

Pilot functionality was demonstrated via the following personas:

Persona	User Interface	Description	Key Capabilities
Supply Chain Analyst	Event Actions	Distributes product across ecosystem partners	• Ship • Receive • Dispense
Quality Analyst	Product Security	Sends and receives product alerts in the event of an investigation into a serialized unit or product lot	• Verify product status • Flag products for investigation or recall • View product alerts
Serialization Analyst	Drug Provenance	Views whether the drug product has been shipped, received and/or dispensed	• Trace the provenance of a drug product

Table 5: User personas and associated capabilities in Pilot design.

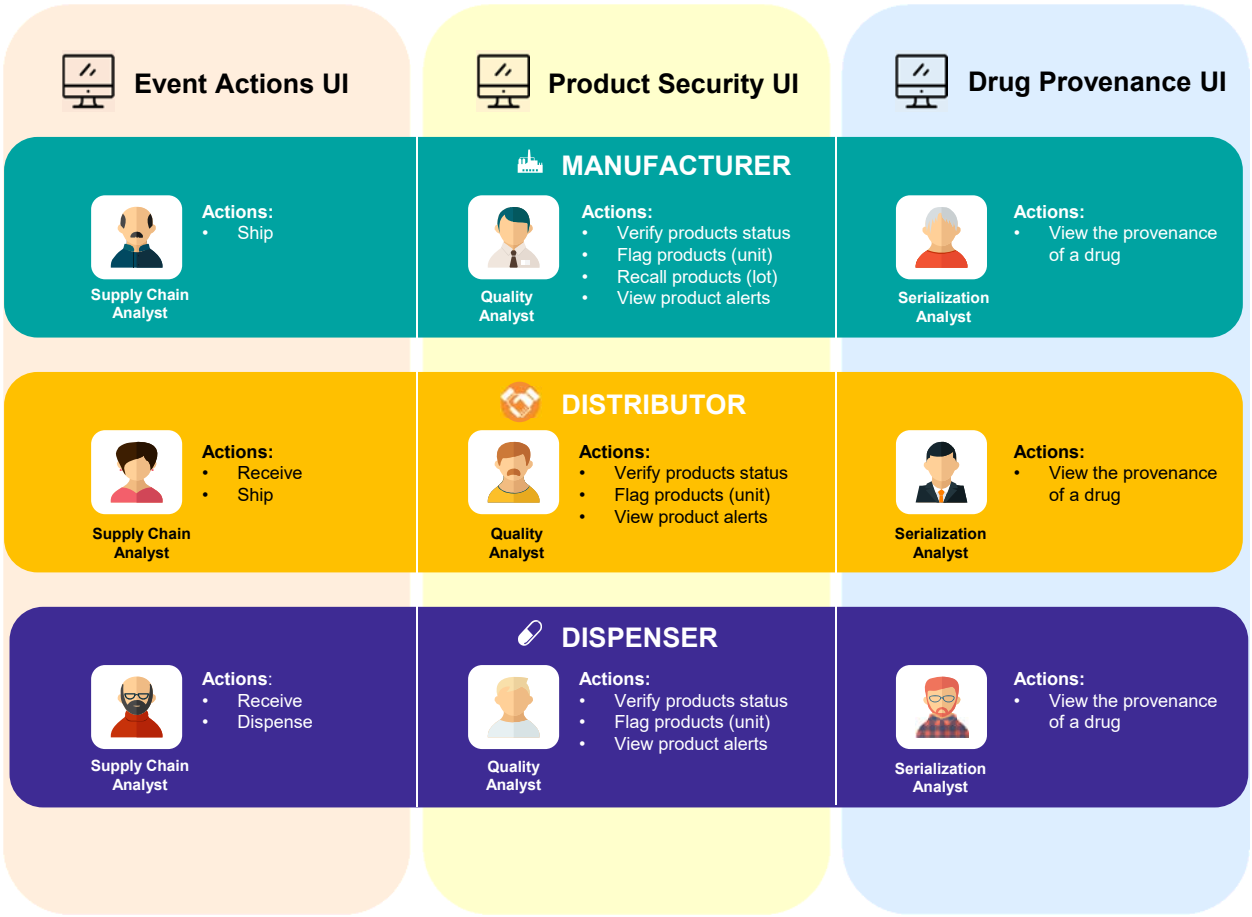


Figure 6: The different personas represented by each organization, the actions each persona may take, and the user interface they will use to take action.

Functional Requirements (Page 5 of 5)

Assumptions:

- Participants are legitimate and appropriately credentialed

Processes

Actions identified for each persona are consistent with the Electronic Product Code Information Services (EPCIS) GS1 standard observation events:

	Manufacturer	Distributor	Dispenser
Commission	✓		
Ship	✓	✓	
Receive		✓	✓
Dispense			✓
Verify	✓	✓	✓

Figure 7: The organizations that had permission to complete each process in the Pilot.

Processes out of scope for the Pilot:

- Decommission
- Reverse distribution including verification requests related to DSCSA Saleable Returns Verification requirement
- Partial dispense

User Interactions (Page 1 of 4)

The following diagrams show how each user interacts with user interfaces to execute key functionalities.

Figure 8 depicts how each organization's user personas can record product movement actions that are recorded in an immutable ledger on the blockchain.

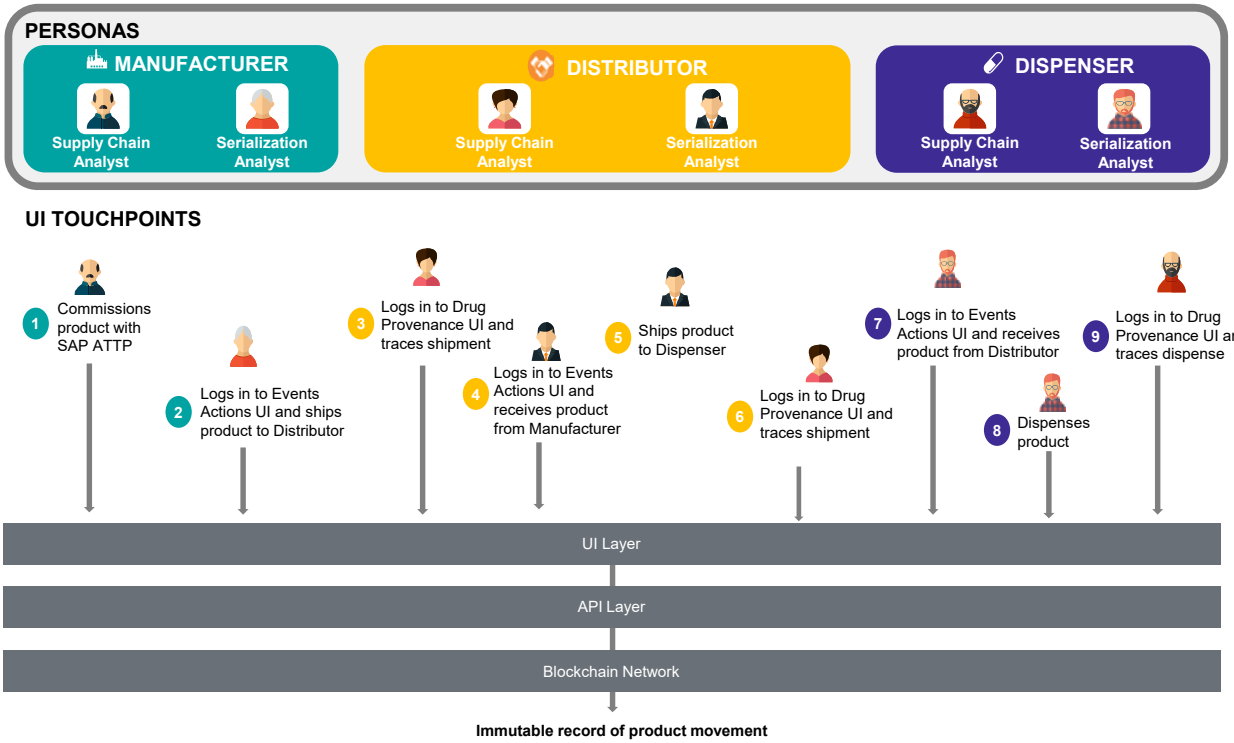


Figure 8: Figure shows how the Supply Chain Analyst and Serialization Analyst may commission, ship, receive, dispense, and trace product.

User Interactions (Page 2 of 4)

Figure 9 depicts how a Quality Analyst is able to instantly verify a product identifier and its associated status (e.g. “Under Evaluation”, “Under Investigation” or “Recalled”).

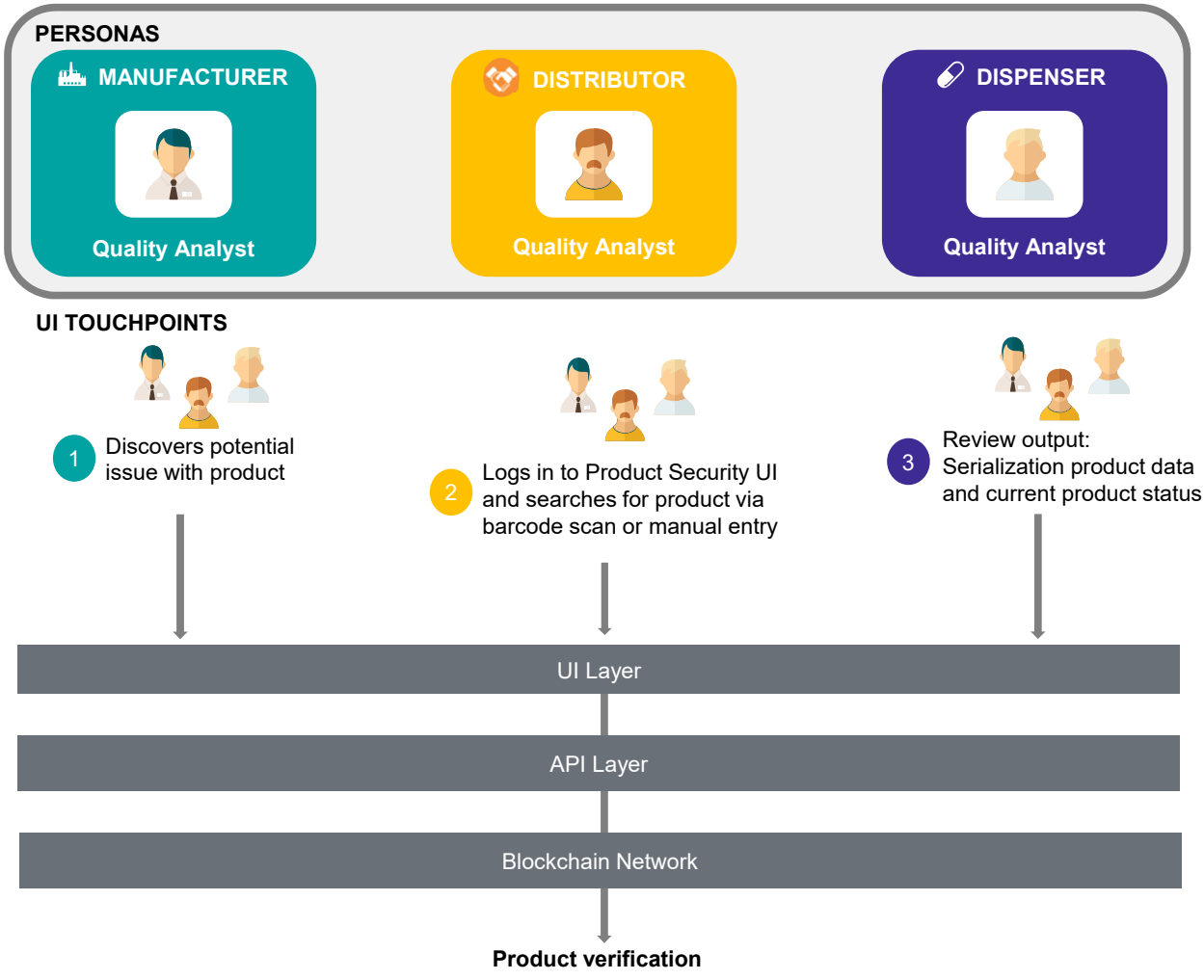


Figure 9: Figure shows how Quality Analysts may send and receive near-real time alerts related to product status to other network stakeholders.

User Interactions (Page 3 of 4)

Figure 10 depicts how each organization's user can trigger alerts for products resulting in prevention of further shipment or dispense.

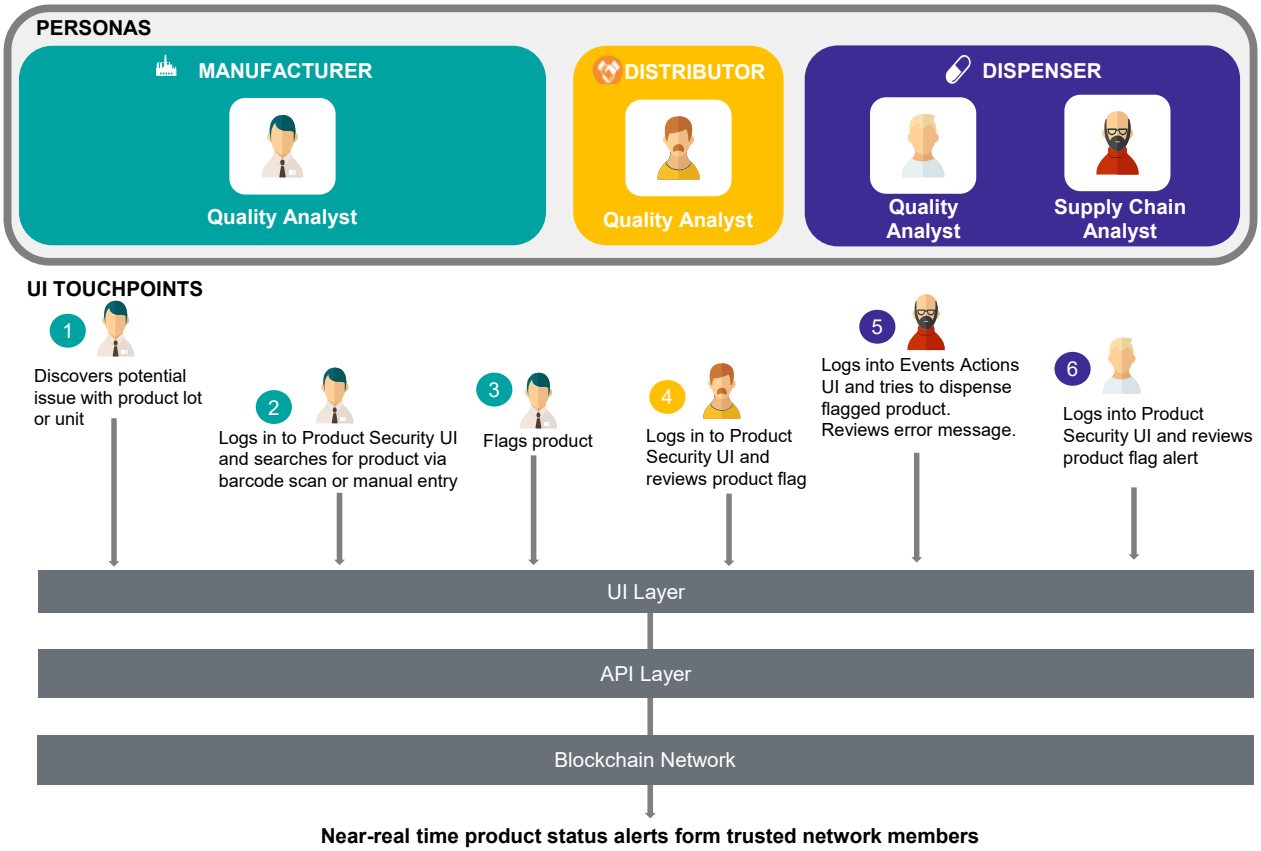


Figure 10: Figure shows how alerts prevents further shipment and dispense of product subject to alert.

User Interactions (Page 4 of 4)

Non-Functional Design Considerations

The system was designed with the following non-functional considerations in mind: availability, latent capacity, performance, scalability, security, and serviceability.

System Qualities	Description	Related Technical Requirements
Availability	A measure of how often a system's resources and services are accessible to end users, often expressed as the uptime of a system.	• The system shall be available 99.9% of the time 24x7
Latent Capacity	The ability of a system to handle unusual peak load usage without additional resources.	• The system shall asynchronously batch large data loads and respond that the load has been accepted within 10 seconds
Performance	The measurement of response time and latency with respect to user load conditions.	• The system shall return a verify request to see a products validity within 7 seconds • The system shall provide the capability to flag a product and the flag should be visible to all affected parties who possessed the product within 1 minute • The system shall respond to all search / trace API calls within 7 seconds 95% of the time • The system shall respond to all search / trace API calls within 15 seconds 99% of the time
Scalability	The ability to add capacity (and users) to a deployed system over time. Scalability typically involves adding resources to the system but should not require changes to the deployment architecture.	• The system shall be able to handle unusually high loads at peak times with zero loss of data • The system shall be designed and implemented with elasticity so it can be scaled up and down to meet current and future scalability requirements
Security	A complex combination of factors that describe the integrity of a system and its users. Security includes authentication and authorization of users as well as the secure transport of information.	• The system shall restrict all data and transaction visibility to members of the blockchain • The system shall restrict all data and transactions data to members who own the data or are specifically granted access to the data • Members must have signed, verifiable identities issued through a trusted certificate authority provider
Serviceability	The ease by which a deployed system can be administered, including tasks such as monitoring the system, repairing problems that arise, and upgrading hardware and software components.	• The system shall utilize automatic deployment and self-tests utilizing DevOps principles • The system shall allow deployments with zero down time • The system shall employ self-monitoring mechanisms with alerts in cases of service • The system shall allow Operators to monitor the health of the system and review relevant logs

- The following non-functional considerations were out of scope for the Pilot:
- Full network system integrations (Merck ATTP integration is the only integration in scope)
- GxP compliance
- Interoperability between blockchain protocols
- Single sign on (SSO) or enterprise authentication and authorization
- Enterprise integration for security
- Content management of data

Solution Architecture (Page 1 of 1)

The Pilot solution leverages a blockchain to capture, record and share relevant pharmaceutical supply chain information and product alert statuses between and across three types of organizations: manufacturer, distributor, and dispenser. The Pilot solution supports three user-facing web applications with which users can interact with the blockchain network in accordance to their designated role.

- **Event Actions UI**: A web application that provides the ability for network members to ship, receive and dispense drug products
- **Drug Provenance UI**: A web application that provides the ability for network members to view the provenance of a drug product
- **Product Security UI**: A web application that provides the ability for network members to verify a product and send/receive product-related alerts

The Pilot end-user experience abides by the design principles defined by the U.S. Digital Service for the U.S. Web Design System version 2.0 (USWDS2).[7]

The Pilot solution is comprised of a foundational blockchain platform layer which utilizes existing IBM Food Trust (IFT) assets on Hyperledger Fabric. An API extension layer connects IFT assets with the user-facing web application layer. The Pilot solution also demonstrates the capability to integrate with Merck's SAP ATTP system and publish commissioned products to the blockchain.

- **Blockchain**: An implementation of a private permissioned blockchain using IBM Hyperledger Fabric on IBM Cloud
- **API**: Application Program Interfaces (APIs) to submit transactions and inquire data to/from the blockchain network
- **Integration**: Data integration between the blockchain network and Merck SAP ATTP

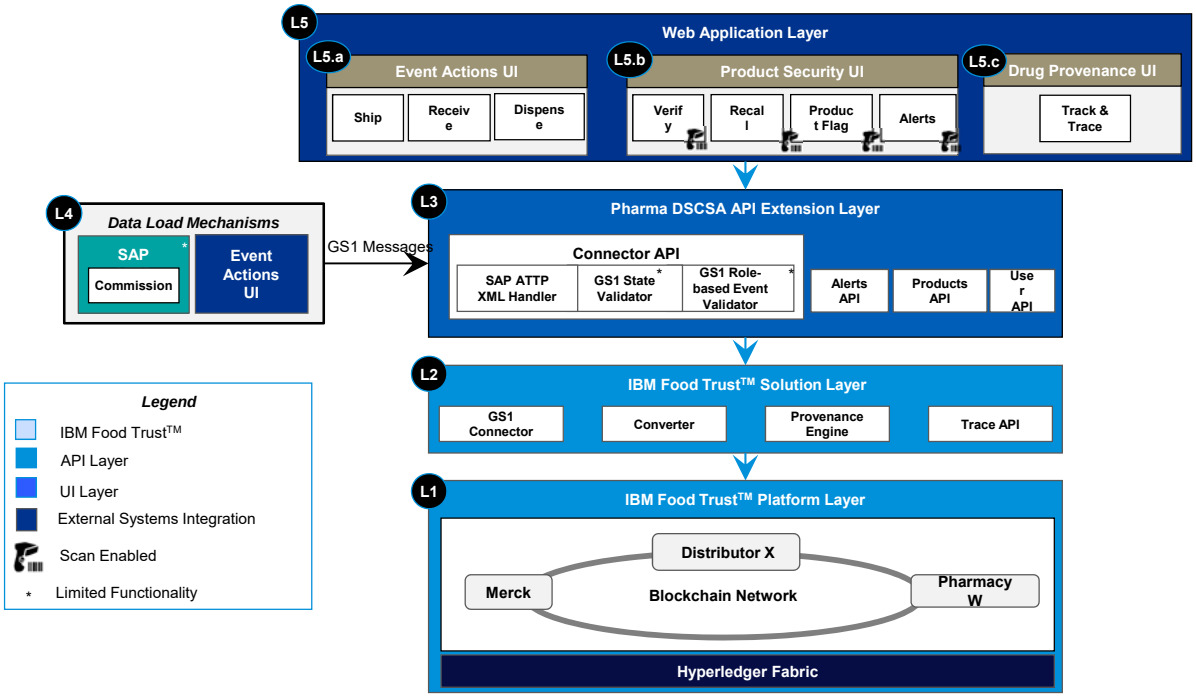


Figure 11: Solution architecture diagram of all components.

Reference

7 https://designsystem.digital.gov/about/design-principles/

Solution Architecture Details (Page 1 of 4)

L1: IBM Food Trust (IFT) Platform Layer

The Pilot leverages IFT solution architecture, as it provides proven features and functions:

- Proven platform and code base
- Built on IBM Blockchain and Hyperledger Fabric
- Provides reusable assets that also help future-proof the platform
- Provides provenance/traceability in a high performant manner
- Conforms to GS1 standards including EPCIS events
- Provides a GS1 connector

Depending on the network user's use case, the IFT system can be designed to have multiple nodes. The Pilot was designed with three nodes represented by the manufacturer, distributor and dispenser organizations. All data submitted by participants was stored on-chain while copies of this data may be stored in off-chain caches optimized to address particular queries. The official "master" copy of the data is always stored on-chain and the off-chain cached data is re-created from the on-chain master.

L2: IBM Food Trust (IFT) Solution Layer

The IFT Solution Layer includes several key components for utilizing a blockchain solution in the supply chain industry.

- **GS1 Connector**: The GS1 Connector provides an API to send GS1 EPCIS 1.2 XML messages to the system. The system validates the XML, puts the messages on an asynchronous message hub to be processed by the IFT Platform Layer (L1) and written to the blockchain.
- **Converter API**: The Converter API allows users to upload an Excel file in a specific format to be converted to a GS1-compliant message.
- **Trace API**: The IFT Solution Layer provides many additional sets of APIs. The Pilot specifically leveraged the Trace API for tracking and tracing products.

L3: Pharma DSCSA API Extension Layer

The Pharma DSCSA API Extension Layer is utilized by the Data Load Layer (L4) and Product Security UI (L5). This layer serves as an intermediary between external applications and the IFT Solution Layer (L2). The following components are leveraged in this solution layer:

- **Connector API**: The connector API is a NodeJS-based API. It takes the incoming requests, validates product state, and passes validated requests to the IFT Solution Layer L2 GS1 Connector.
    - **Merck ATTP XML Handler**: This layer consumes the commissioning EPCIS event sent from Merck ATTP via ICH. It transforms the XML into a valid GS1 XML messages, validates the XML, and passes the validated XML to the IFT Solution Layer (L2) GS1 Connector.
    - **GS1 State Validator**: This layer checks that the state is valid before sending it to the IFT Solution Layer (L2). If the state is invalid, it passes back the appropriate error message to the caller. Examples of state validation include duplicate dispense, attempt to dispense a product that is not saleable, or shipping of a product that is not saleable.
    - **GS1 Role-based Event Validator**: This layer checks that the user who has logged in to the API has a role that matches an appropriate event type. For example, only a manufacturer can commission a product and only a dispenser can dispense a product.
- **Alerts API**: The Alerts API is a NodeJS based API. The API takes incoming alert flagging requests, validates them, and passes validated requests onto the IFT Solution Layer (L2). Additionally, the Alerts API provides a recent history of alerts and the current status of products that have been subject to one or more alerts. Alerts can only be seen to relevant parties that have possessed the product. Please see the "Product Alerts and Permissions" section for more details on Alerts.

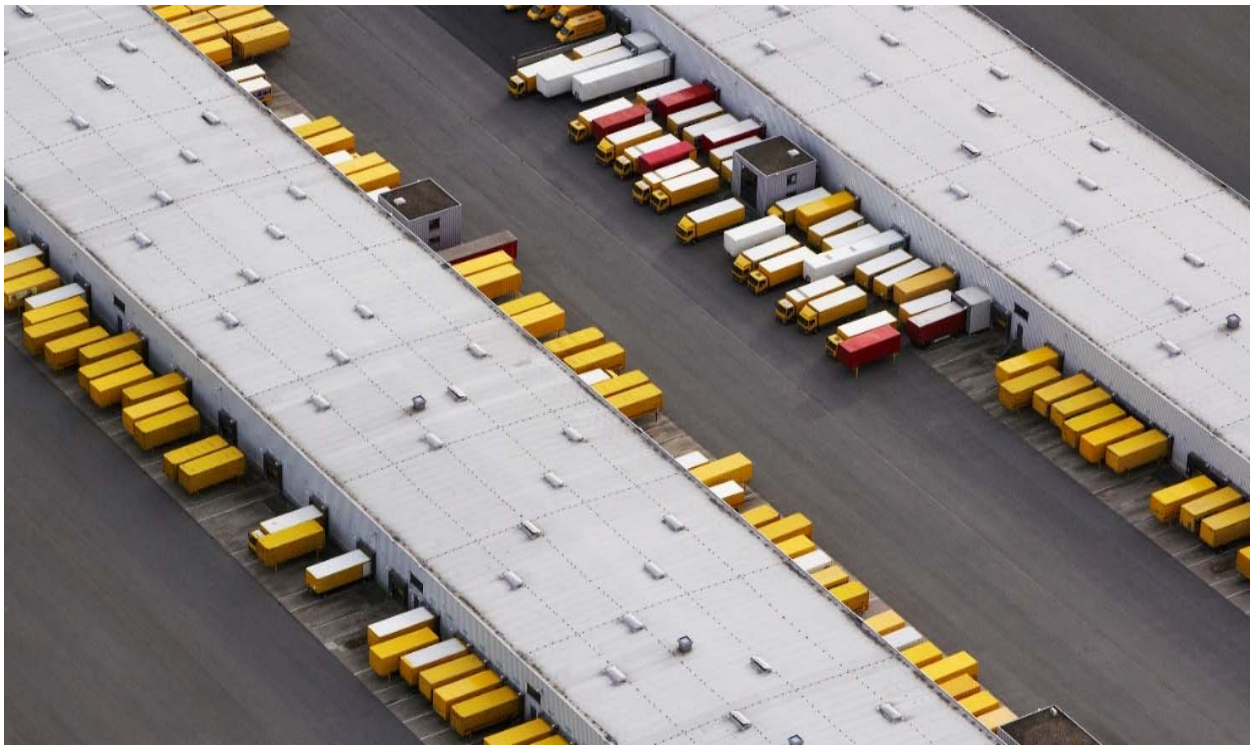
Solution Architecture Details (Page 2 of 4)

- **Products API**: The Products API is a NodeJS based API. It is used to verify or trace a product. The products API utilizes the IFT Solution Layer Trace API to identify which organization is currently in possession of the product.
- **User API**: Applications use the User API for system authentication. Additionally, organization administrators can use the User API to create, update or revoke user access. The User API interacts with IBM Cloud Identity Access Management system.

L4: Data Load Mechanisms

The Data Load Layer SAP ATTP and the Event Actions UI to load data into the blockchain system.

- **SAP ATTP**: The SAP ATTP/ICH layer submits product data to the blockchain via a commissioning event. First, ICH uses a specific system ID to authenticate with the Pharma DSCSA API Extension Layer (L3). Next, it sends the Merck commissioning XML to the Pharma DSCSA API Extension Layer (L3) Connector API via an HTTPS post.
- **Event Actions UI**: The Event Actions UI is hosted outside of IBM Cloud by KPMG in Microsoft Azure Cloud. It is used to simulate back-end systems by sending GS1 EPCIS distribution events for a manufacturer, distributor or a dispenser. The events in the Pilot include shipping, receiving and dispensing.



Solution Architecture Details (Page 3 of 4)

User Interface	Actions (s)
a. Event Actions UI	• Ship • Receive • Dispense
b. Product Security UI	• Verify product • Flag products • View product alerts
c. Drug Provenance UI	• View the provenance of the drug

Table 6: User interfaces in web application layer.

L5: Web Application Layer

a. Event Actions UI

The Event Actions UI enables each organization's Supply Chain Analyst to submit distribution events other than commissioning to the blockchain. Manufacturers may ship product, distributors may receive and ship product, and dispensers may receive and dispense product. If an authorized Supply Chain Analyst attempts to ship, receive or dispense a product that is subject to an alert, the Event Actions UI displays an alert and prevents the user from completing the action.

b. Product Security UI

The Product Security UI enables each organization's Quality Analyst to verify and flag products. The UI includes the following functions:

- **Verify**: A user may verify a serialized unit by either a barcode scan or manual entry of the product's four key identifier fields (GTIN, lot number, serial number, expiry date). The Verify function will return the current state of a serialized product (i.e. "Saleable", "Under Evaluation", "Under Investigation", or "Recalled").
- **Recall**: The Recall function enables a manufacturer to recall a product lot. It also provides an information export function that can be used to export details about locations of the serialized products in the recalled lot so that users can pinpoint potential areas of risk.
- **Flag Product**: The Flag Product function enables users to flag a product as "Under Evaluation", "Under Investigation" or to reverse a product that is subject to an alert to "Saleable". For more information on product flagging, please see the "Product Alerts and Permissions" section.
- **Alerts**: The Alerts function enables a user to see the complete alert history of a verified product, the recent alerts relevant to the user's organization, and a list of products with associated product status that recently have been subject to an alert. Alerts are only visible to organizations that possess or have possessed the product.

c. Drug Provenance UI

The Drug Provenance UI enables each organization's Serialization Analyst to trace the provenance of a pharmaceutical product. This layer interacts directly with the IFT Solution Layer (L2). The Trace function enables the user to search by lot or serial number to view the provenance of a product or products. In the Pilot solution, transaction visibility was limited to "one up, one down" to simulate the current data sharing practices of the pharmaceutical trading partners. For example, a manufacturer can see product commissioning, shipping and the distributor's receipt of the shipped product (s).

Since capturing aggregation and disaggregation events was outside of Pilot scope, the packing event is used to associate a lot with the serial numbers within the lot and will not be necessary in the future once the ability to capture aggregation events is integrated. The distributor can see the manufacturer's shipping event, the distributor's receiving event, the distributor's shipping event, and the dispenser's receipt of the shipped product(s). The dispenser can see the distributor's shipping event, the dispenser's receiving event, and dispenser's dispensing event.

Solution Architecture Details (Page 4 of 4)

Data Standards

The Pilot leveraged GS1 standard EPCIS 1.2 events.

Data Type	Description	Standard
Master Data	Facility (location)	GS1 Standard
	Product (item)	
EPCIS Events	Commission	GS1 EPCIS Standard
	Shipping (Observation)	
	Receiving (Observation)	
	Dispensing (Observation)	
Payload Data	Generic string-encoded payloads	FDA Pilot Specific (Alerts)
User Data	User information (login, mapping to IFT system users)	FDA Pilot Specific, Off-Chain Storage

Table 7: Types of data standards and descriptions.

Solution Testing (Page 1 of 2)

The Pilot was tested in the following phases:

1. Unit testing (UT)
2. Functional testing (FT)
3. System integration testing (SIT) for SAP ATTP integration
4. User acceptance testing (UAT)

All UT, FT and SIT were completed with resulting defects remediated and known system behaviors communicated before the UAT session.

User Acceptance Testing (UAT) was conducted by representative members of each Pilot organization. The testing began with loading data into the system via SAP ATTP and ended with a synthesis of test findings and learnings.

The Pilot was tested using data representing the following pharmaceutical products:

Product	GTIN	Lot	Expiry Date
Zostavax	**00300064963007**	ZSTV4001	2020-08-31
		ZSTVS3001	2021-10-31
Vaqta	**00300064831412**	VAQ2001	2021-04-30
		VAQ1001	2021-01-31

Table 8: Pharmaceutical products data used during solution testing.

Test Data Flow

The image below is an example of the flow of data used in testing:

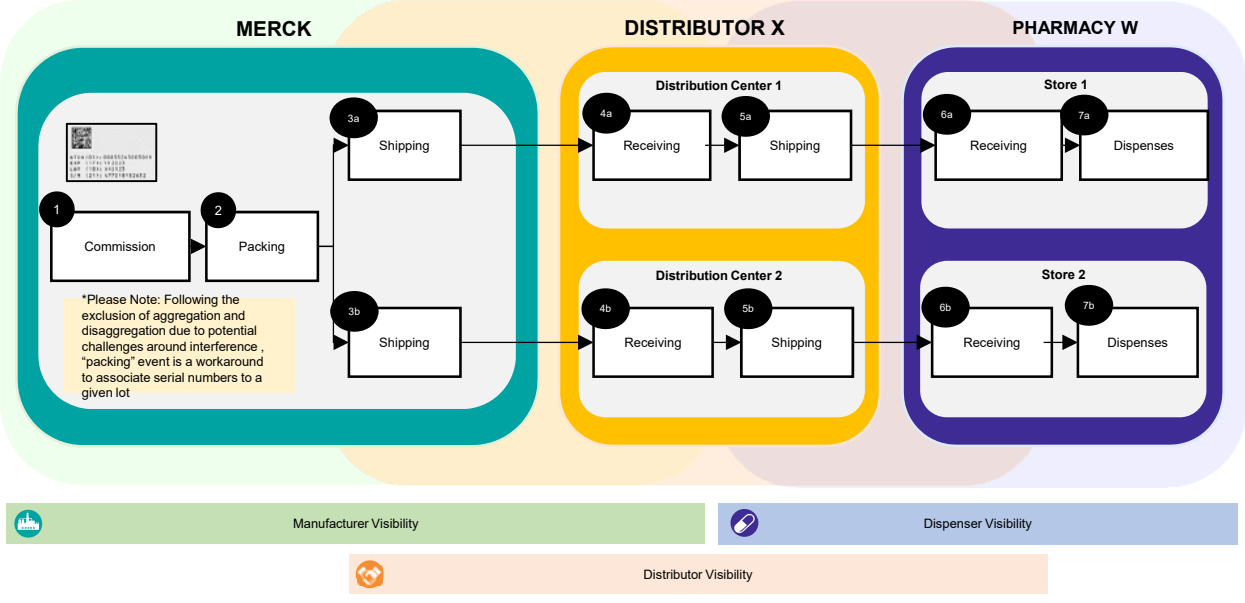


Image 12: Test data flow and data visibility (one up, one down) used for testing the Pilot.

Solution Testing (Page 2 of 2)

The team tested the following scenarios during UAT:

Scenario	Description
Scenario 1: Trace	User can search for a product to view its trace history (product details, from GLN / to GLN, date, time).
Scenario 2: Verify	User can verify a product by passing the Product Identifier. Must be demoed with a barcode scan (default) with optional manual input option.
Scenario 3: Under Evaluation	User can flag a serialized unit as "under evaluation" and alert any network members who have taken possession of it.
Scenario 4: Under Investigation	User can flag a serialized unit as "under investigation" and alert any network members who have taken possession of it.
Scenario 5: Recall	Manufacturer can flag a lot as "recalled" and alert downstream network members who have taken possession of it.
Scenario 6: Flag Reversal - Under Evaluation to Saleable	User can reverse a previous "under evaluation" flag of a serialized unit to "Saleable" and alert any network members who have taken possession of it.
Scenario 7: Flag Reversal - Under Investigation to Saleable	User can reverse a previous "under investigation" flag of a serialized unit to "Saleable" and alert any network members who have taken possession of it.
Scenario 8: View Most Recent Org. Alerts	User can view a list of most recent alerts relevant to their organization.
Scenario 9: View Product Alerts	User can view a list of products with associated alerts relevant to their organization.
Scenario 10: View Alert History	User can view a list of all prior and current alert statuses associated with a verified product.
Scenario 11: Information Retrieval for Recall	User should be able to retrieve information from the blockchain related to the traceability of a recalled batch.
Scenario 12 (Exception): Potential Duplicate Transaction Error	User should not be able to dispense a product that has already been dispensed.
Scenario 13 (Exception): Submit Transaction on Flagged Product	User should not be able to ship or dispense a product that is subject to an alert (under evaluation, under investigation or recalled).

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