DSCSA & Blockchain: Phase 2
Proof-of-concept pilots

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BLUE TEAM (Chronicled)
"Using a distributed blockchain network for compliance & innovation"

Overview

The Blue Team (Chronicled) is developing a distributed platform to be *owned and operated by industry* (including trade partners and service providers) to demonstrate its ability to meet all track & trace requirements, as well as be a platform for future business process innovation. This demonstration covers all movements of the drug up to the point where it is removed from the manufacturer's packaging/unique identifier. Its design is based on the initial commissioning, then change-of-ownership, of the unique identifiers. This Pilot will demonstrate how the industry can use the blockchain to 1) Execute salable returns verification, 2) Meet the interoperable 2023 system requirements, 3) Block/eliminate counterfeits

Team's vision

The mission of this pilot is to demonstrate to an audience with varying knowledge of blockchain the possibilities of this technology to solve problems that have not been solvable with currently used technology. Additionally, the Team looks forward to sharing its overall vision for the digital ecosystem. That is, how blockchain can connect the industry, and how each industry segment can benefit through these connections.

PURPLE TEAM (Intel Corporation, iSolve, Excellis Health)
"Creating a 360° View of the biopharma supply chain with Digital Ledger Technology"

Overview

This pilot is designed to demonstrate how digital ledger technology is *complimentary* to existing track & trace solutions. It demonstrates a blockchain-based, end-to-end tracking solution (from manufacturer to patient) that can be used to easily transfer data from one party to another, improve operational efficiency, and create a positive impact on patient outcomes. The Team demonstrates a fully viable 2023 interoperable solution that meets the regulatory requirements of DSCSA and beyond. Pilot will demo *interoperability, saleable returns, drug recall, supply chain integrity,* and *borrow & loan.*

Team's vision

The Purple Team's mission for its PoC Pilot is to take a holistic view of the supply chain – linking manufacturer to patient by building an interoperable connection between all trusted participants in a modern biopharma supply chain, including: Manufacturer, Wholesaler, Pharmacy/dispenser (health system, community/rural hospital, retail), and Patient.

GREEN TEAM RxTransparent, Systech
"Blockchain: A viable end-to-end solution for the pharma supply chain"

Overview

Systech and RxTransparent represent both ends of pharma supply chain manufacturers and dispensers, respectively. With their unique industry insights and perspectives, they came together as a team to build a pilot platform that demonstrates blockchain as a viable solution for compliance with upcoming DSCSA interoperability system requirements. The presentation is designed for a broad audience of stakeholders across the entire life sciences and healthcare spectrum including manufacturers, wholesalers, dispensers, regulators and logistics providers.

Team's vision

This PoC is based on the fundamental principle that an interoperable DSCSA platform will utilize blockchain as a component of the overall industry solution by harnessing blockchain's strengths and avoiding the technology's weaknesses.

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ORANGE TEAM (Cryptowerk)

"<u>The Power of Many</u>: Blockchain interoperability and portability for DSCSA Compliance"

Overview

The Orange Team Pilot proposes how a secure open source storage system housing encrypted and non-encrypted data can be used in conjunction with blockchain and other distributed ledger technologies to meet the data exchange requirements of both the DSCSA and the industry at large. This open-source, blockchain-validated solution is focused on interoperability and scalability in heterogeneous trading partner environments. It is designed to allow partners to securely store, validate, and exchange product tracing information and is intended to be complimentary to existing track & trace solutions. Additionally, it optionally leverages the superior security of public blockchains at scale for data integrity validation.

Team's vision

Today, the pharmaceutical industry leverages a variety of different serialization and supply chain providers to track and trace their products. It is this team's position that the industry will prefer to leverage existing heterogeneous solutions rather than agree upon one single solution for the industry. Additionally, the team believes that no one company should hold the trust of the entire community and therefore proposes an open-source framework – validated by one or more blockchains of choice – to cryptographically store and share data.

AQUA TEAM (Axiom Technology Group)

"Answering the 'Where's My Stuff?' question for the pharma supply chain"

Overview

The team has designed an enterprise-wide blockchain solution for asset traceability and data transparency that allows unrelated parties to have end-to-end visibility across the value chain regarding transfer of ownership, business events and transactions. Participants can share pertinent business information via a distributed system, allowing them to share cryptographically assured data across a secure supply chain network. Pilot Platform is built utilizing Oracle Blockchain Cloud Solution (BCS) to provide an end-to-end asset traceability solution. Business logic will be applied and implemented via chain codes (Smart Contracts) and combined with analytics to dashboard the asset information. Utilizing the "product-centric" ReferenceModel #3 developed in "DSCSA & Blockchain Phase 1" Study, the team employs an Oracle BCS-based blockchain infrastructure to *augment* existing business systems.

Team's vision

The team set out to create an end-to-end asset traceability solution to benefit and advance the pharma supply chain. By integrating enterprise blockchains with existing business applications, the pilot demonstrates the seamless integration of business information to a distributed ledger, allowing for custom deployment hosting via enterprise cloud platforms. They the industry to collaborate and provide feedback so that it can create a viable blockchain technology solution to benefit all stakeholders.

YELLOW TEAM (Authentag, Accenture)

"<u>Beyond Compliance</u>: DLT implementation lessons learned & supply chain optimization potential"

Overview

This PoC demonstrates how an immutable chain of custody and granularity of ownership can reshape logistics. Will show current advances enabled by FDA led GS1 GTIN and PI labeled unique identification and demonstrate full 'creation to end use' traceability through all parties in the supply and use network. Will analyze current real usage of FDA Regulated GS1 GTIN + PI uniquely labeled traceability and how full traceability is already being used for more than just FDA compliance. Real examples then illustrate why a distributed ledger and blockchain are necessary and suitable as part of a traceability solution for the pharma industry.

Team's vision

For an open source, community owned and community governed digital ledger that manages transactions and traceability for all actors within the pharma community, whilst providing isolated data protection and multi-party contracts that can adapt overtime with regulatory and business needs.