

Blockchain to eliminate counterfeit drugs and medical devices and aid an advanced supply-chain traceability layer

Pharmaceutical companies are heavily impacted by patent risk and safety concerns arising from the counterfeiting of drugs, leading to brand damage and deteriorating consumer trust. And with increasing import and export of pharmaceutical drugs from markets prone to counterfeiting of pharma products, the need for a sound and traceable supply chain is imminent.

The healthcare industry is unsettled concerning accountability and security over frequent frauds of counterfeit drugs and medical devices. Such scams lead up to 8 percent of drugs and medical devices to turn up fake copies in circulation today, ultimately impacting profits, brand reputation, and opportunity loss to your healthcare company.

The Drug Supply Chain Security Act was introduced to address the issue of counterfeiting drugs and other pharmaceutical devices. Let's learn more about this Act.

FDA & DSCSA's role in addressing counterfeiting of drugs and medical devices

The Drug Supply Chain Security Act was enacted on 27th November 2013 with a ten-year deadline for implementing an action plan to build an electronic and interoperable ecosystem to identify and track prescription drugs from manufacturing to dispenser receipt.

Pharmaceutical manufacturers, the market authorization holder (MAH), are mandated to encode unique serial numbers and other applicable data associated with the product (Global Trade Item Number – GTIN or National Drug Code - NDC, lot number, and expiration date) on retail units and homogenous cases provisioned to the market. In addition, manufacturers must maintain systems to corroborate serial numbers and transaction history to support an inquiry. Today, the encoded data are retained in an interconnected electronic record utilized for verification proposals and are currently hosted in the manufacturer's internal systems. Hereafter, the serialization data must be communicated with trading partners as the product progresses throughout the supply chain among distributors, 3PLs, re-packers, and dispensers.

What are the challenges faced by DSCSA?

Today, the pharmaceutical supply chain comprises 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 retail 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 and investigate and respond to FDA inquiries in support of suspect/illegitimate product investigations. However, without a centralized host of authority 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.

Now let's look at how Blockchain will enable restricting counterfeiting of medicine and medical devices.

What are Blockchain Benefits for fighting counterfeiting of medicine and medical devices?

Via smart contracts and off-chain data, Blockchain can operate large quantities of data and fosters scalability across multiple extents: participants, transaction volume, and product type. Smart contracts are digital manifestations of business-driven contracts that reside on the Blockchain. Smart contracts represent the association between two or more parties. They can stimulate the automation of business functions among network members, eradicating operational inefficiencies by automation and delivering more remarkable accuracy. For example, in future iterations of the Pilot, a smart contract could facilitate automatic product re-ordering if a product is vandalized in transit or enable payment to be released from sender to recipient upon confirmed receipt of the product. A blockchain network might get developed to maximize the benefit of off-chain storage. For instance, a blockchain network may employ off-chain storage to store personal identifier details to streamline compliance with HIPAA or facilitate sharing of large files or documents. In addition, Blockchain may deem off-chain storage to maximize search query efficiency. Regardless, network designers must guarantee that the search capacities allowed by the off-chain database stick to the network's existing authorization structure. The cryptography ingrained in Blockchain promotes an immutable and verifiable chain of custody that can be employed to support product investigation. Parties can also independently confirm products without reaching out to the manufacturer or other trading partners. Further, network stakeholders could appoint a digital twin of a physical influence on Blockchain by integrating Blockchain with other

technologies such as internet of things sensors (IoT) or ultra-high-resolution cameras. The digital twin could be leveraged to characterize an immutable ledger of product geolocation or temperature data and could also improve patient safety by guaranteeing that the product label has not been counterfeited.

Blockchain helps Pharma companies to trace and track supply chain, end point distribution, thereby eliminating counterfeit drugs, associated patient risks and cost impact. It further prevents brand reputation damage and loss of revenue for the company.