The epidemic of counterfeit pharmaceuticals entering the supply chain is a serious cause for concern. Counterfeit drug products can lead to lawsuits, damage a brand's image, and, most importantly, cause potentially serious health consequences for patients. The problem has sent pharmaceutical manufacturers in search of serialization methods to increase security at multiple points along the drug product supply chain. Many companies are relying on technologies that enable them to track and trace products from the manufacturing plant to the medicine cabinet.

This article discusses blockchain’s potential as an anticounterfeiting tool in the pharmaceutical industry.
One possible solution that stands out as a strong defensive measure with inherent tracking capabilities is blockchain technology. Blockchain is a method of permanently and verifiably recording transactions and storing those records in a decentralized peer-to-peer network so they cannot be retroactively altered. However, blockchain is still in its infancy, and implementing the technology poses challenges to the current digital infrastructures of many pharmaceutical companies. In this article, three industry experts share their insights into whether blockchain technology may be a useful tool to counter the counterfeiters and protect the drug product supply chain.

Tom Egan, vice president–industry services, PMMI: As counterfeiting efforts continue to become more sophisticated, distinguishing real drug products from imitations is increasingly difficult. Often, counterfeiters steal expired products, then repack and relabel them with falsified dates and dosage information. Merely examining a product’s packaging and corresponding labels is no longer sufficient to verify its authenticity, especially as the machinery used to repack these products is often as advanced as that of the original manufacturers.

As a result, pharmaceutical companies—along with manufacturers from many other industries—are turning their attention to blockchain as a possible solution that will create an easy-to-follow trail of verification. Successfully implementing blockchain technology would allow the industry to verify each transaction along the supply chain and securely store product information, preventing unverified drug products from entering the system.

However, real-world application of blockchain is still in the concept phase. While this technology may prove to be a viable way to track and trace products, pharmaceutical companies may hesitate to implement it due to the wide availability of product information to anyone in the supply chain with access to the network. Still, if advancements to the technology and process alleviate those security concerns, blockchain may become a viable method of combating the growing epidemic of counterfeit drugs.

In the meantime, pharmaceutical companies are putting their eggs in multiple baskets by exploring other technologies for counterfeit prevention, including the use of covert tags with radio frequency identification technology (RFID), barcodes, or web portals that can be checked when products arrive at a facility. This helps companies verify the authenticity of their products after distribution.

In 2013, the FDA announced the Drug Supply Chain Security Act (DSCSA) to strengthen the impact of serialization. To meet the FDA’s new requirements, many companies began pilot tests using cameras to track packages with an embedded code, enabling traceability. However, without established industry standards to follow, companies have struggled to create a system. To address this hurdle, the FDA continues to work to implement other provisions of the DSCSA to serve as additional guidelines for serialization, but validation exercises could take months or even years, and the resulting solutions may not enable consumers to easily verify product authenticity in the way that blockchain could.

Rick Fox, president and chief executive officer, Fox IV Technologies: The appeal of blockchain lies in the creation of a trusted network resting on a cloud-based environment that is nearly impossible to hack. Many companies pursuing higher supply-chain security struggle to reach that standard. In fact, in 2017, only 15 percent of pharmaceutical manufacturers in Europe reported that they would be able to implement an appropriate serialization process by the deadline mandated in the EU Falsified Medicines Directive [1]. Some companies addressed the supply-chain security problem by developing proprietary internal systems to combat counterfeiting. However, such systems are still susceptible to hacking due to their reliance on passwords for data entry.

Although blockchain is still in its infancy, its potential to improve serialization has not gone unnoticed. In enforcing the DSCSA, the FDA has begun calling for pilot programs using blockchain technology [2]. This could inspire the industry to implement blockchain within the next five years. It’s possible that by 2023, blockchain technology may no longer be referred to theoretically in the pharmaceutical industry but rather as a realistic solution for drug counterfeiting. In the meantime, packaging suppliers are ready, willing, and able to help implement blockchain to advance pharmaceutical supply-chain security.

Bill McBeath, chief research officer, Chainlink Research: Companies attempting to deter counterfeiting of their products can consider both serialization and non-serialization anti-counterfeiting methods. Non-serialization methods include hard-to-forge markers on either the dosage form or packaging to authenticate drug products. However, the DSCSA mandates serialization to combat counterfeits. As of November 2018 (after the FDA delayed enforcement for one year), all pharmaceuticals in homogeneous cases must be serialized and compliant with the FDA’s standardized numerical identification guidance [3]. The DSCSA also requires that, by November 2019, wholesalers must
accept only serialized pharmaceuticals and, by 2020, dispensaries must also only accept serialized pharmaceuticals. It remains to be seen whether these requirements will be rigorously enforced on this timeline. An October 2018 assessment by GS1 found only 20 percent of pharmaceuticals to be fully compliant [4].

While blockchain may eventually offer a solution for establishing a secure traceability process for pharma, many companies are forging ahead using other, much more mature and proven technologies for serialization and traceability. Additionally, the blockchain data structure is extremely slow for searching. Using blockchain for traceability will require a shadow database optimized for searching for instances such as product recalls or to find the chain of custody for a particular serialized unit. In fact, users will need to combine blockchain with a number of other technologies to achieve the desired results. Blockchain does provide strong immutability, however, meaning that, once written, the data can never be modified. That provides a very robust audit trail that can help deter fraud in the supply chain.

References


PMMI is the association for packaging and processing technologies (571 612 3200, www.pmmi.org). The association represents more than 850 North American manufacturers and suppliers of equipment, components, and materials as well as providers of related equipment and services to the packaging and processing industry.