Linking Pharma Manufacturing: CDMOs, Blockchain & Distributed Ledger Technologies (DLT)

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Executive Synopsis

The term blockchain is most often associated with cryptocurrencies such as Bitcoin, but the technology and its implications could have a more far-reaching impact on other industries including pharmaceutical manufacturing. Contract drug manufacturing organizations (CDMOs) and pharmaceutical developers could realize tangible benefits by implementing a variant of blockchain termed "Distributed Ledger Technology" (DLT). DLT promises to provide better transparency within the pharmaceutical supply chain, create cohesive hand-offs, increase traceability, and prevent fraud or counterfeiting. There are several ways to implement DLT within a pharma supply chain, including FDA mandate or guidance, leadership from a pharmaceutical company or consortium, or ecosystems that self-organize. Major challenges in executing a DLT include platform integrations, cost, governance, and accountability. To explore theoretical DLT applications, we illustrate using the drug product manufacturing fill and finish CDMO ecosystem of Argonaut Manufacturing Services.

How is blockchain different than DLT?

Simplified, a blockchain is a continuously growing chain of records that are cryptographically linked. Each record ("block") contains a link ("hash") to the previous block, a time stamp, and transaction data. Once data has been recorded in a blockchain, it is essentially impossible to alter undetected. If the data inside a block changes, so does its hash. To change one block, a hacker would have to change all blocks in the chain (this video[1] easily explains blockchain). Additionally, blockchains use a peer-to-peer network (each peer is a "node") to verify the integrity of the chain, using "consensus" algorithms as each new block is added. When consensus is reached, all nodes add the new block. The layering of hash, peer-to-peer networks, and consensus algorithms provide security in the chain and transaction integrity.

Blockchain can be defined as a decentralized digital record of transactions which records information permanently, with verification. This definition highlights three key features of blockchain. The first is *decentralization*. The data is stored in multiple nodes across a network of computers, as opposed to centralized storage where data is stored in a single location in the network. The advantage of decentralization is that there is no single point of failure. If one computer goes down, the others retain all the data. Furthermore, if one participant is a bad

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