# DESIGN IS DEAD
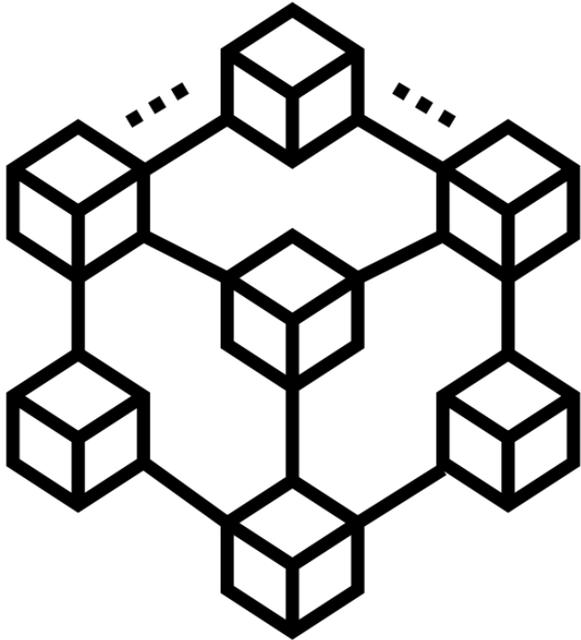
## BLOCKCHAIN IN PHARMA

BATTLING COUNTERFEITS AND ENSURING QUALITY
THROUGH PROVENANCE

# Blockchain Technology

Over the last two years blockchain has emerged as one of the key technologies that will greatly disrupt several industries. Organizations are quickly realizing the positive impact of adopting this emerging technology.

## Data silos

Traditionally businesses rely on large centralized databases and cloud infrastructure to store and process their data. These databases present many problems in an increasingly connected world. They're often siloed, making it difficult for multiple parties to settle on a single verifiable truth for all parties to agree on.

Relationships between suppliers, regulators, partners and customers are increasing in complexity rapidly. In order to manage these relationships, trust is needed. Traditionally that trust is provided by third parties or the lack of it is handled by risk management.

In a context where data is siloed it needs to be reconciled first and all parties need to settle on an agreeable single truth, slowing down transaction times and increasing their cost.

## A Network of Trust

Many organizations are examining blockchain technology to overcome the issues with purely centralized architectures. With blockchain, data isn't stored on a centralized database but instead stored and automatically replicated and shared across a network of databases and upheld by a consensus mechanism between peers.

This network is transparent and verifiable, allowing anyone that is signed into it to see a single source of truth on current and historical data. It also improves the efficiency, accuracy, and speed of transactions, minimizing disputes, and the need for intermediaries.

Exciting new use cases are merging across many industries enabled by blockchain, including supply chain. Finance, where users are in full control over their financials and no longer have to rely on banks. Provenance of assets become a verifiable, traceable and auditable, creating transparency throughout the lifecycle of a supply chain. The medical industry personal ownership of medical records that can be used universally at the person's discretion. Creative content ownership and distribution, where creators are not exploited by intermediaries, and receive direct compensation for their work.

# Lab to consumer performance

Developing pharmaceutical products is a complex process consisting of many interrelated business activities. We'll look at how blockchain can provide a meaningful and holistic solution for managing the product lifecycle and chain of custody. This enables pharmaceutical companies to improve their product lifecycle management and allows regulators, customers and academic researchers better insight into the product origin and drug development history.

## Clinical Trial Inventories

Managing clinical trial inventories is becoming increasingly complex as often external partners and CDMOs are used in the process. Traditional ERP or MES system often lack the flexibility and the possibility of coordination. Disjoint tools across and even within organisations and the lack of a single source of truth adds considerable time and cost to the R&D production phase.

## Origin of the pieces

When bringing a product to market, drug manufacturers are faced with drug registration processes and labelling requirements. This is an extensive administrative process due to an ever increasing volume of regulatory evidence and data associated with the product which is often spread across the organization and external partners. These parties maintain their own separate ledger, making any particular segment of the supply chain difficult to track.

Product origin and labelling is becoming increasingly important for regulators and customs as well as consumers. Better product information and record keeping allows medical staff more insight to make better decisions for their patients. Pharmaceutical companies have a hard time keeping track of their products in the supply chain, allowing counterfeiters to introduce fake products into the system. In developing countries between 10% and 30% of drugs are counterfeit and consumers have little option to verify the origin of the product.

# Chaining The Pieces

Blockchain bring the relationships necessary in the product management lifecycle into a single blockchain network. It's distributed natures enables the complete end-to-end product lifecycle and supply chain management for every product. It enables instantaneous reconciliation and exchange of data between all participants in the pharmaceutical business network that is incredibly robust and secure.

## Quality by design
Direct exchange of information through a shared ledger allows all parties in the R&D and drug development process to manage data effectively, share knowledge and do more accurate and monitoring and quality control. Effectively enabling a quality by design approach.

## Clinical Trial Inventories
Clinical trials are stored in a secure, unfalsifiable and verifiable manner on the blockchain. This prevents tampering with clinical trials results, improving the reliability of the clinical trials data.

Standardization of data formats and the constant availability allows for precise coördination of the chain of custody as this process becomes more difficult and complex.

## Supply Chain Lifecycle
Every participant in the supply chain can directly check and verify the origin of the product as well as associated quality assurance tests and clinical trials.

This allows medical staff to make more informed decisions in real-time. It enables consumers to seamlessly check product information such as expiration date and leaflet and verify the product origin to ensure it is not counterfeit.

## Global Product Registration

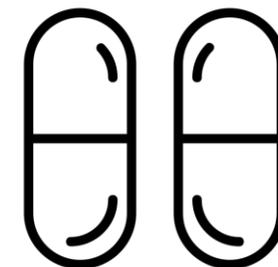**16%** of counterfeit pharmaceuticals contain wrong ingredients

In western countries over **30% of consumers** are concerned about issues regarding product origin but struggle to act

**$200 BILLION**
The total size of the counterfeit drug market

In developing countries **between 10% and 30%** of pharmaceuticals is counterfeit

# SUMMED UP
The business value of blockchain

### Transparent Drug Development Record
A structured archive for each individual dossier in a unified system is needed to effectively manage all of the associated content, capture historical development information and facilitate the re-use of common technical documents.

### Clinical Trial & Supply Management
.Supply chain for clinical trials is rapidly becoming more complex. A complete history of production campaigns must be archived. Distributed ledger technology allows for effective synchronization and integrity of approved manufacturing evidence and trial activity

### Technology Transfer & Collaboration
Drug production requires collaboration across many interrelated activities and dependencies. An enterprise solution that enables the analysis of the drug product value chain including suppliers, materials, equipment, processes and regulation will not only provide individual lot control but also facilitate the scale-up to commercial drug production volumes.

### Global Product Registration
Leveraging the verifiable historical record of a program undergoing regulatory submission can significantly improve the speed of the approval process.

# CONTACT US

And let's improve the drug
development lifecycle, one block at a
time.

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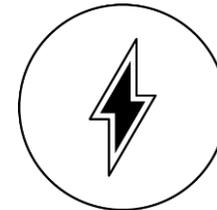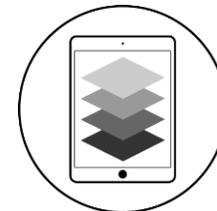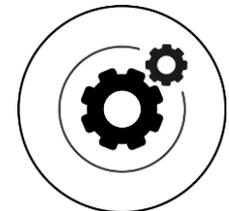
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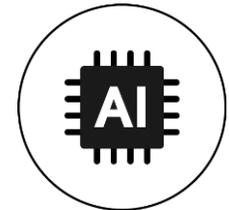
Provide Actionable Insights

Activate Digital Customers

Continuous Automation