



LEVERAGING BLOCKCHAIN AND IOT TECHNOLOGIES FOR SMART MANUFACTURING

Abstract

The paradigm of digital manufacturing is rapidly evolving across diverse sectors owing to numerous benefits, including improved productivity and quality, lower costs, better security and flexible execution models. At the core of digital manufacturing are data and information. Data integrity is ensured as it is generated from machines using Industrial IoT. Furthermore, organizations are looking to conduct remote operations and utilize new suppliers and channel partners for their supply chain ecosystem with the prevailing pandemic. This paper captures Blockchain driven use cases in manufacturing and critically examines the need for stringent data lineage in the pharma industry as it is highly regulated and involves sharing data with multiple partners, including the FDA. Industrial IoT with blockchain helps establish traceability, transparency, and trust. In addition, we explore the confluence of technologies like blockchain, Industrial IoT and IT-OT convergence for designing trusted solutions applicable across diverse industrial sectors beyond pharma.

1. Overview

As part of Industry 4.0, enterprises strive to maximize production through digital transformation. As a result, several industries are undergoing an information-intensive transformation of manufacturing, seamless decentralized connectivity of people, processes, and systems through blockchain, IoT-enabled industrial assets, among many other innovations. In addition, enterprises capitalize on hyper niche technologies to realize benefits of a smart industry and ecosystems of industrial innovation and collaboration.

A digital thread is the interconnected information framework that allows data interoperability, traceability and access to an integrated view of the product representative digital data throughout these lifecycle phases. Thus, the digital thread integrates **personas** (design engineer, operations manager, plant manager, quality manager etc.), **processes** (concept ideation, product design, manufacturing, sales and operations and support/ disposal), **systems** (engineering tools, PLM, ERP, MES, LIMS etc.) and **places** (spatial data).

The smart manufacturing ecosystem encompasses multiple stakeholders through the distributed product supply chain and requires collaboration across the value network starting from R&D, engineering, supply,

manufacturing, distribution and after-sales service. Moreover, regulatory mandates for transparency coupled with rising losses due to counterfeit products flooding the marketplace and reconciliation overheads have forced manufacturers to embrace blockchain.

Blockchain is being explored to offer solutions to longstanding industry pain points. For example, there is a higher chance of delays in complex, cross-constituency supply chains causing issues in supply reliant and logistics sectors. Such delays impact production and profitability. Blockchain in the supply chain can bring about seamless connectivity across multiple stakeholders with a single source of truth, eliminate expensive paper trails, and ensure trust, transparency and traceability, and cost optimization.

Industrial IoT is increasingly deployed for digital manufacturing enabling IT-OT integration to increase manufacturing efficiency and effectiveness. Further, enterprises are using computing capabilities on the cloud, necessitating shop floor data to be integrated into the cloud. These changes have complicated the information exchange between systems. As a result, there is a need for trustworthy data exchange while still recording additional data, collaborating and making informed decisions in quick time.

Some of the key challenges being faced in digital manufacturing are:

- It involves multiple systems and technologies with a host of functions to manage right from mining minerals, material handling, engineering, process control, manufacturing operations, planning, monitoring to warehousing, distribution and retailing. Speed of transactions, establishing trust between systems and ensuring transparency of transactions need drastic improvements
- Data integrity becomes an issue as sensitive production data can be changed or manipulated, creating vulnerabilities in the network.
- Distributed and decentralized information and data involving multiple stakeholders make trust, redundancy, controlled data sharing and improved reliability difficult.

These challenges require careful considerations while digital manufacturing with industrial IoT ensures more automated data and hence data integrity. The Digital Thread concept is to establish the interconnected information framework enabling the information mobility across the life cycle of any product. With this information framework it will be easier to establish data connectors into Blockchain at appropriate life cycle stages of the Digital Thread.

Blockchain technology helps in establishing a trustworthy, immutable, highly scalable and configurable data exchange for the data that is taken up from the Digital Thread information framework.

2. Key Use Cases of Blockchain and IoT Combined

Blockchain and IoT jointly in supply chain use cases deliver several benefits across industries such as transparency, accelerated turnaround and cost optimization through product provenance.

This section presents an insight into blockchain and IoT for several industry use cases:

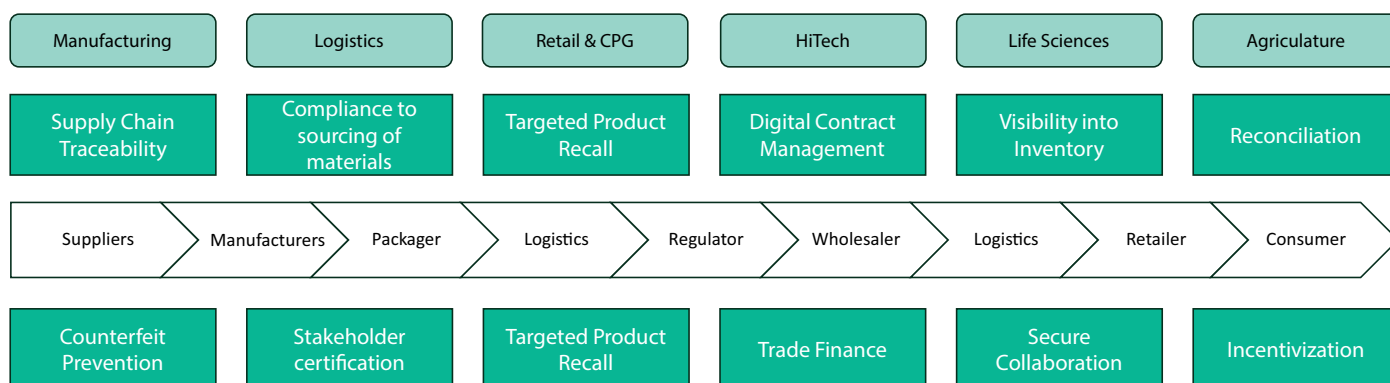


Figure 1 Industry use cases for blockchain and IoT

2.1. Traceability in the Pharma Industry – Drug provenance and Recall

Drug counterfeits cost over USD 200 billion for the pharmaceutical industry. About one million people die owing to fake drugs every year. The World Health Organization (WHO) estimates that 8 percent of the medical devices in circulation today are counterfeit. So, naturally, pharma regulatory authorities globally increasingly seek to control the pharma supply chain. They intent to protect the population from the adverse effects of counterfeit and substandard pharma products.

As the need to ensure a critical supply of drugs, vaccines and medical devices around the globe intensifies, the pharma industry must recognize the potential of blockchain to transform drug traceability in the supply chain ecosystem radically. Blockchain based traceability and provenance can eliminate counterfeit drugs from the pharma ecosystem. In addition to increasing trust, transparency and efficiency of the value chain, blockchain can empower patients opting for clinical research and trials in coordination with public health and regulatory authorities.

Certain pharmaceutical products are mandated to adhere to strict ambient parameters during transit. A blockchain

based solution can prevent drug recalls or assist targeted recalls due to **mislabeling, contamination and failed specifications**. In addition, it can provide a more secure and transparent way to report on changes to the operating conditions of transported pharmaceutical products. All participants and authorities in the supply chain would use this to ensure better compliance.

2.1.1. How does IoT help in the Process?

Current Good Manufacturing Practice (CGMP) is a set of regulations enforced by the FDA. It ensures that manufacturers have followed practices for drug production and have processes for monitoring and controlling it. Documented proof must be submitted to the FDA. As a result, the quality and purity of the product are assured.

Some of the critical questions to ask of the CGMP process include

- Are activities documented at the time of performance?
- Can only authorized individuals make changes to records?
- Is there a record of data changes ?
- Is data maintained securely from creation through disposition after the record's retention period?

Digital manufacturing or industrial IoT integrates both machines (through automation) performing a process into systems and the personnel involved and their activities. As a result, it provides complete data integrity and transparency. Blockchain is employed to establish traceability in this complex chain with multiple handoffs, ensuring easy access to traceability information and the chain of custody.

There is no manual intervention and mutation of the CGMP data with production data coming from machines. Getting this data on a ledger based on blockchain will ensure immutability and trust and serve as a proof of record during FDA audit for consumers and suppliers.

- **Suppliers** – will get an assurance that their raw materials were obtained from sub-suppliers, their origin, thoroughly quality tested and approved before being used for the manufacturing of the drug
- **Consumers** – will get an assurance of the chain of record of the manufacturing process, quality test data
- **FDA** – will get the record of CGMP for audit purpose



Pharma Supply Chain – Functional Architecture

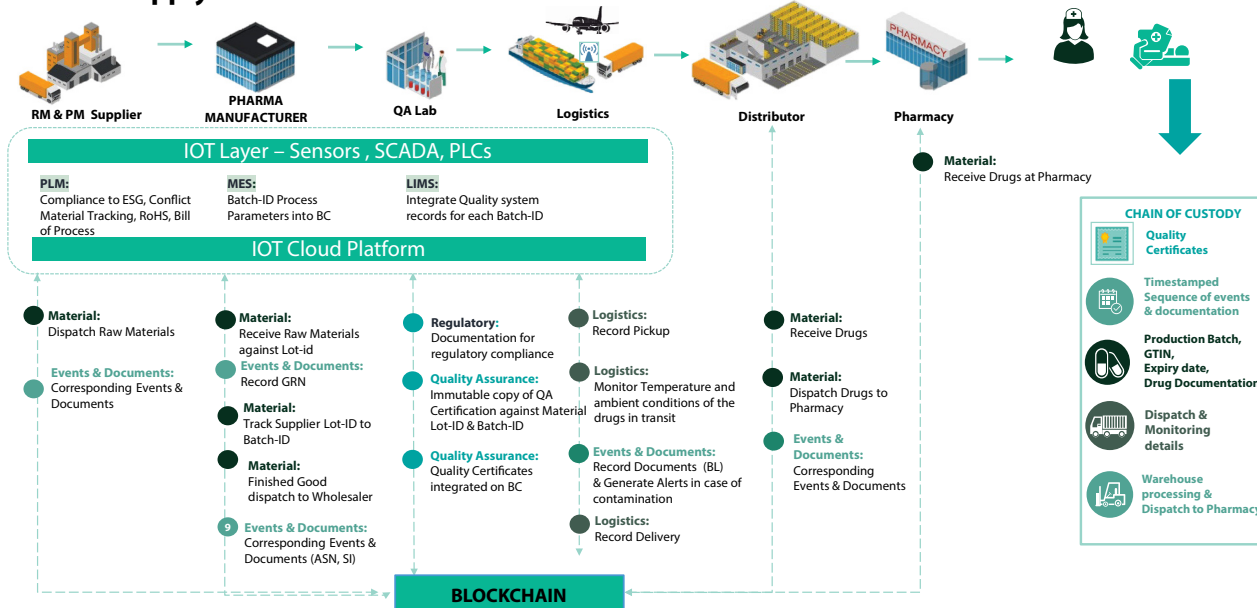


Figure 2 Pharma Supply Chain – IoT and Blockchain Integration

The entire process shown in Figure 2 involves capturing the real-time production events in a blockchain during each step. In addition to machine data, IoT device data from RFID and barcode systems automate the capturing of the production flow and process flow changes, validating its authenticity and quality. This involves multiple stakeholders and systems recording data about these transactions along the material's path to the manufacturing plant and customer. Above all, data integrity and trust across the value chain to meet regulatory compliance are critical.

There are interoperability challenges as there are no real standards in data exchange. However, heterogeneous machines, devices, business systems and databases are used in the pharmaceutical supply chain necessitating seamless interoperability.

Blockchain in Pharma captures data across the life cycle from raw material supply, manufacturing, production, shipment, logistics to retailers. This immutable data is visible to all the stakeholders.

2.2. Traceability in Manufacturing and Supply Chain

Many regulated industries like food and beverages, aerospace and hi-tech require traceability of each material or item, right from the source to the end-product.

Quality checks, handling, processing and final transformation into the product need to be tracked and traced with the relevant metadata of transactions. This ensures stringent quality controls to meet compliance. It also prevents counterfeiting, confirming the authenticity of products available to the patient.

The electronics industry is incentivized to keep a close watch on the origins of conflict minerals (tantalum, tin, tungsten and gold, or "3TG,") because of the US Securities and Exchange Commission's (SEC) "Conflict Minerals Rule." This rule, codified under Section 13(p) of the Securities Exchange Act of 1934[10] (the "Exchange Act"), applies to companies that use minerals, including 3TG. If a company reports to the SEC that such minerals are "necessary to the functionality or production" of a product manufactured or contracted to be manufactured by the company, the Conflict Minerals Rule applies. The rule requires companies to conduct a good faith and reasonable "country of origin" inquiry that is reasonably designed to determine whether any of the products manufactured or contracted to be manufactured by the company originated in the Democratic Republic of Congo (DRC) Region or are from scrap or recycled sources. In addition, the supplier must confirm the origin of minerals and declaration for SEC compliance.

The importance of traceability can be gauged by the fact that counterfeiting is rampant in

the pharma industry and is estimated to be a USD 106 billion market growing at 12% CAGR.

2.3. Blockchain for Information Integration

Smart manufacturing requires integration across the automation layers, from the devices to shop floor controls, manufacturing applications and enterprise systems. These devices range from smart transducers for temperature, humidity, pressure, flow, position barcode readers, RFID cameras, motor and pumps and industrial machines and lab equipment. The data from the transducers are networked to reach the fog or edge node and can involve wired or wireless sensing networks. Communication protocols vary from Ethernet, Wi-Fi, Zigbee, Bluetooth and NFC.

The prime requirements are robust connectivity, interoperability and data integrity at the device level. The connectivity needs to be robust and requires a mechanism to secure them and make them tamper proof. It can be addressed using blockchain technology which supports immutability and has distributed architecture. Moreover, blockchain renders it tamper proof and improves data availability, essential for IoT data integration.

Blockchain is used to authenticate IoT devices and get capability-based access to the devices. The capability can be device identification, configuration, logical access to the network or local interfaces and software updates.

2.4. Traceability of spare parts

Enterprise blockchain is purpose fit for establishing irrefutable traceability of individual parts in a manufacturing supply chain spanning the supplier to the end consumer. The blockchain enabled immutable chain of custody captured over a distributed ledger ensures that once a part number is uniquely recorded at a node, this tamper proof digital twin can be linked to its physical part and updated by subsequent stakeholders for easier reconciliation and a near real-time view.

Such a network connecting part suppliers, OEMs, manufacturers, 3PLs, distributors, dealers and service centers can also help track counterfeit parts more effectively, enhance integrity around parts lineage and improve overall transparency across the value chain. In addition, the post sales life cycle of high value parts can be tracked more effectively by linking records of service, repair, resale and scrappage. This provides a holistic picture of parts usage before its end of life and establishes a concrete view of reusing and recycling of these parts as they are dismantled and resold in the secondary market.

The automation brought in by smart sensors can greatly enhance the operational efficiency in the entire process, as blockchain receives trusted inputs from these parts and intelligently links information updates to provide an unalterable and integrated view of spare parts across various stakeholders.

Predictability in resource availability and resource consumption is essential to drive efficiencies on the shop floor and maximize capacity utilization. Hence, two of the key use cases where IoT is utilized are:

Driving **predictive maintenance of assets** that are critical for the production operations with high costs of repair

Automation of inventory tracking and reporting shortage - Once a need for maintenance is predicted, the solution will use real-time inventory and spare parts information and trigger a purchase request

based on the current inventory stock. This is especially critical for the MRO industry, where the range of spare parts can be highly diverse. Hence real-time monitoring of spare parts inventory is essential for on-time delivery of repaired vehicles or assets. In the MRO industry especially, counterfeit spare parts are a big challenge and procuring genuine spare parts is a critical success factor for the repair. Blockchain triggered by the manufacturer and updated by the distributor, 3PLs and freight forwarders, can be exploited for a secure and trusted spare part inventory system. Further, IoT can be harnessed using devices or RFID tags attached to the spare parts for traceability. Thus, a combined IoT and blockchain solution can bring about traceability and immutability in the spare parts business.

Impact on business KPI due to traceability can be in terms of improved utilization of assets upto the extent of 20%, increase productivity to the extent of 5%.

2.5. Product Life cycle Management with Blockchain

A typical product life cycle entails an elaborate product planning phase, development and launch, and an equally extensive post-launch management. The FDA mandates design control procedures that capture the user needs, intended uses and the design activities, including verification, validation, design transfer as documented evidence. In addition to product management, development and marketing departments within a product organization, several other external entities and third-party contractors play their part through the ideation, implementation and post-sales support of a product.

With its ability to connect disparate systems within and outside the organization, blockchain can form the underlying conduit that connects and integrates the data captured across product stages. In addition to product updates, management of product licenses and their usage can be tracked more effectively as

tamper-proof records can be maintained on the network.

Compliance tracking is also an important aspect of product life cycle management, with organizations expending substantial efforts to comply with newer regulations and geo-specific mandates. A blockchain ecosystem, bringing product organizations and regulatory authorities on the same network, can form the structured data storage that records the compliance requirements and how they are being met. In addition, the process can be made more seamless through blockchain, receiving digital inputs from IoT devices and using smart contracts to trigger actionable notifications in case of deviations, delays and non-compliance.

A new product launch follows a complex concept to market life cycle from the ideation phase to consumption by the end customer. A safe and successful launch requires integrated data management and easy access to a large volume of information. For example, each CPG product goes through an ideation phase, followed by concept design, product development, artwork or package design, compliance checks, manufacturing and supply chain distribution processes. The data flow spans PLM, LIMS, MES and ERP systems and design systems. In addition, each product goes through a stringent compliance process in a highly regulated industry like CPG. Therefore, there is a need for structured storage of data across the ecosystem players for better traceability and faster response time in case of non-compliance. In addition, the suppliers hold information about the environmental, social and governance aspects. These aspects will be formally accounted as product information that consumers critically review before consumption. Blockchain in conjunction with PLM systems can play a critical role to in providing an end-to-end secure and trusted collaboration between the different systems involved and delivering traceability and security of information.

2.6. Food and Perishable Goods tracking using Blockchain

FDA's Food Safety Modernization Act (FSMA) requires stakeholders in the food business to capture key data elements (KDEs) across critical tracking events (CTEs) to prevent food borne illnesses. Using blockchain across the food supply ecosystem to record the origin of raw produce, packaging, transformation and distribution can help achieve this.

Blockchain can ingest and harmonize transactions from upstream and downstream stakeholders and, in tandem with IoT sensors monitor temperature and humidity conditions during storage and transportation. Near real-time updates can be shared with appropriate stakeholders on the blockchain network if and when necessary conditions for perishable goods are breached in a cold chain. Integrated dashboards can receive aggregated data from the blockchain to provide a granular view through their farm to fork journey for food items. In addition, they can trigger warnings when deviations occur to quickly track and remove food items unfit for consumption from the supply chain.

A blockchain network powered by IoT provides trusted details about food quality and key ingredients to aware end

consumers. In addition, they have improved visibility into the provenance of food items, and sustainability practices followed.

Assuring consumers that their food was handled hygienically and safe for consumption is a legal requirement in the farm to fork life cycle. This includes both meat and farm produce. There are multiple parties with multiple handoffs in this entire chain. Having a trusted data exchange that is transparent, traceable and trustworthy across all the parties, farmers, food processing companies, logistics, warehouses, retailers can be only achieved using blockchain. IoT technology in each stage of the lifecycle - tagging meat with RFID, tracking cold chain trucks using GPS and IoT devices for monitoring temperature and air quality, handling processed meat in the warehouse and retail stores, eliminates data integrity issues. Having this data on blockchain at every stage will make it trustworthy for everybody.

2.7. Tracking of Energy Loss and Carbon Emissions using IoT and Blockchain

Tracking of Energy Loss:

IoT can significantly reduce energy losses across the transmission and distribution space. An energy management system

can harness IoT to track real-time energy consumption and forecast. It can be used to analyze the energy demand pattern in smart grids and manage microgrids. However, given the vast expanse of a grid, it is challenging to securely collect and process data from IoT devices on a grid. Blockchain can enable a decentralized repository of information from multiple IoT devices. In this way, blockchain can form the platform to monitor energy consumption and transactions in a secure and immutable way. Even a combination of IoT and blockchain can help set up a peer-to-peer energy transaction platform that can be used for energy trading.

Tracking of Carbon Emissions:

The effect of greenhouse gas emissions across the globe is forcing countries and industries to redesign their manufacturing process and reduce their carbon footprint. The first step in this process is to understand the current situation and monitor carbon emissions. However, despite international agreements, there is a lack of a global and standardized system to track and measure carbon emissions across the supply chain. Carbon emissions calculations are complex, manual, costly and time-consuming and suffer from a lack of a standardized computation process.

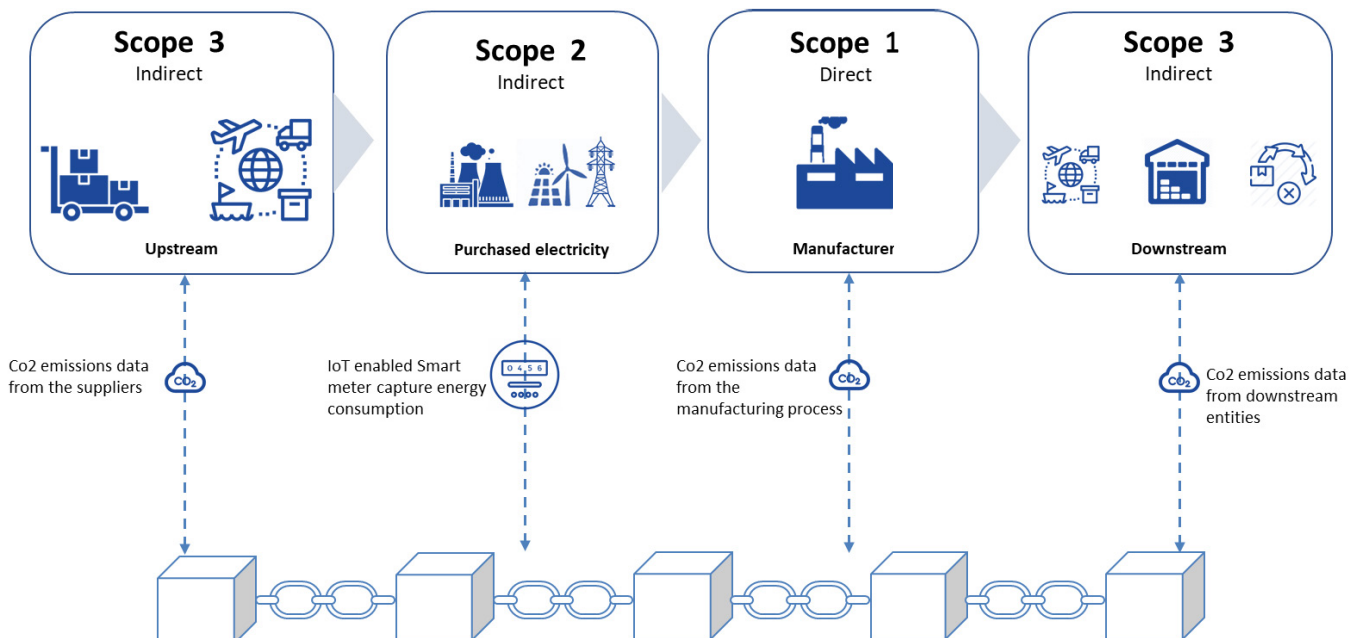


Figure 3. Tracking of Energy Loss and Carbon Emissions using IoT and Blockchain

Blockchain based solution helps companies meet the demand for accurate, reliable and standardized information for carbon emissions. It helps to connect different stakeholders of the supply chain like suppliers, manufacturers, and logistics service providers on a single network. Each party will be able to report carbon emissions across the individual value chains, thereby creating a single platform for carbon emissions measurement that guarantees privacy, security and traceability. Further, it can be integrated with source systems like ERP and SCADA to simplify data gathering across the supply chain, improving visibility at lower cost, time and effort.

2.8. Driving Behavior based Insurance using Blockchain

“Pay as you Drive” is a paradigm shift in automotive insurance. Insurance buyers (drivers) want to be rewarded for good driving. Therefore, they prefer dynamic model based on driving behavior over a fixed premium model.

This is possible if a trusted data exchange exists between the driver and the insurance provider. OEMs manufacturing the vehicles can set up a platform where data from the vehicle is curated in a telematics platform (IoT) and onto a blockchain ledger. This data can be related to speed, traffic rule violations, location, driving patterns, lane

diversion, and other types of real-time data sourced from the IoT solution in the vehicle.

The trusted data exchange serves as an immutable, transparent and traceable source of information for the insurance providers to determine driving behavior and compute the premium.

3. Integration of Industrial IoT to Blockchain

Approach towards integration of IoT to Blockchain IoT enables real-time automated data from things, people, process and systems, thereby ensuring data integrity. Approach towards integration of IoT to Blockchain

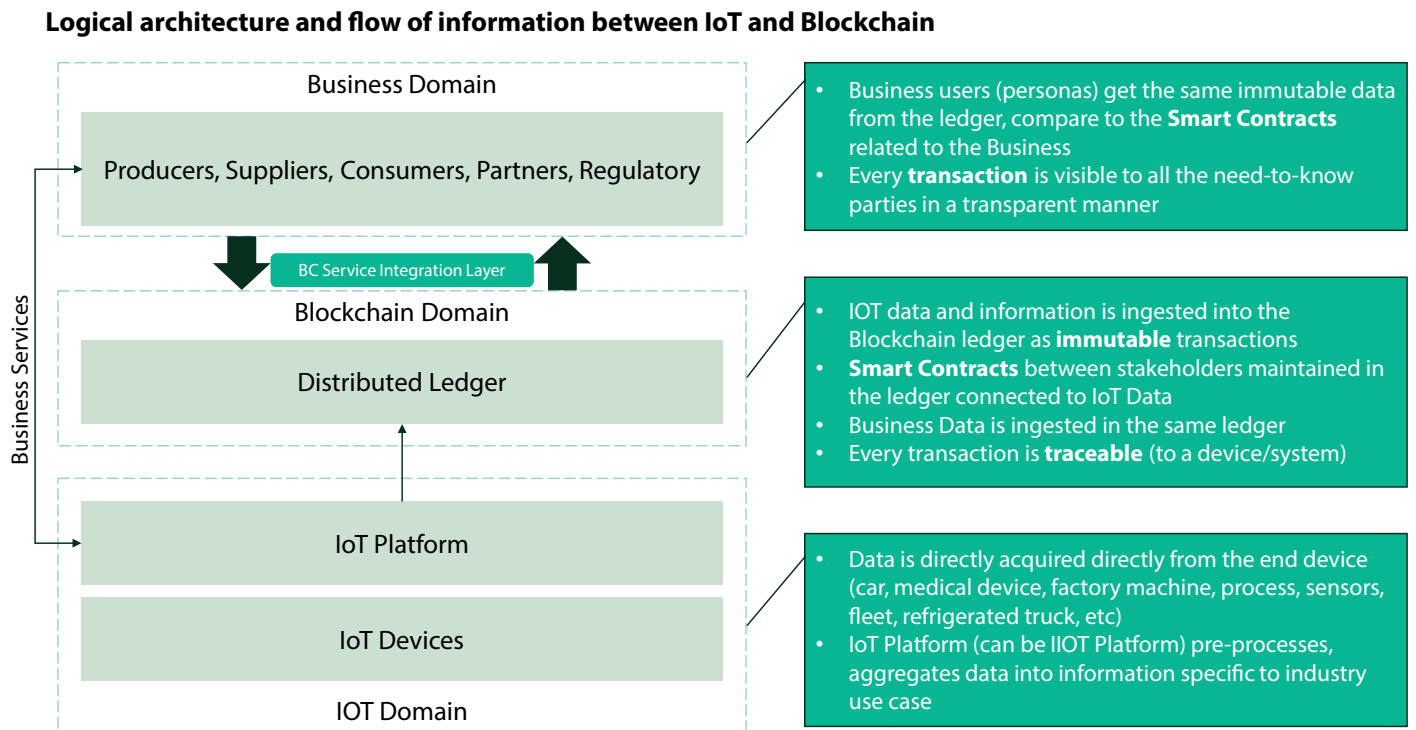


Figure 4. IoT Blockchain basic Architecture

4. Conclusion

Next-gen technologies like blockchain and IoT help customers create capabilities that radically improve operational efficiency and reduce costs. With growing demand in production across the sectors, there is also a higher risk in terms of adhering to the compliance like tracking of conflict minerals, Good Manufacturing Process (GMP) in pharma and so on. The promise of Blockchain technology in establishing the trusted data exchange is helping industries to comply to these requirements. The industrial manufacturing sector is developing innovative blockchain and IoT backed solutions in its digital transformation journey. With IoT the data integrity is established as the data is coming from sensors and machines.

Blockchain can maintain a single and real-time record of information that maps product and component journeys through the manufacturing and distribution value chains. This helps identify gaps and improve supply chain responsiveness. When stored on the blockchain, such information becomes an immutable record easily shared between various stakeholders, driving trust, transparency and effective compliance. In addition, powered by insights through AI, companies can take the right action.

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Abhishek Goyal is a Senior IT Consulting Leader and Executive having 24+ years of overall experience globally. Currently, he serves as a Vice President at Infosys and Global Practice Head for IoT, Blockchain and Digital Engineering Service and Solutions. His role involves creating, selling and delivering Digital Engineering consulting and IT services and solutions in the field of Industrial IoT, Industry 4.0, Consumer IoT, Smart Workspaces, Smart Products, Operational Technologies, MES, MOM, MPS, LIMS, Contact Center, Unified Collaboration, PLM, ALM, CPQ, Knowledge-Based Engineering, AR, VR, MR, Autonomous, Additive Manufacturing, Robotics, GIS, POS, etc. He is a proven thought leader and holds a US patent.



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