

Blockchain Pharma Supply Chain Traceability Transformation

**A Guide How to Ensure Your Supply Chain Regulatory Compliance
in an Innovative, Cost-Effective, and Hassle-Free Way**

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Introduction



Ensuring traceability in the supply chain has always been a key component of a robust and responsible pharmaceutical ecosystem. It is pivotal for patient safety, counterfeit prevention, fostering transparency, general business efficiency, sensitive data protection, and the trust of customers and partners.

Before, tracking and tracing of drugs have been the sole responsibility of the industry players. However, with several countries having passed laws aiming to enhance the visibility of pharmaceutical products as they move from manufacturing to the patient, most chief supply chain officers (CSCOs) are now under pressure to ensure end-to-end drug data sharing before the looming deadlines.

And, to this point, several industry-specific challenges arise. These include fragmented networking, lack of interoperability, outdated infrastructure, and cost implications, not to mention the fact that regulatory requirements vary from country to country. That's why many industry insiders are struggling to translate their supply chain transformation ambition into an understandable, easily implemented, and business-aligned action plan. Hopefully, new technologies are here to help.

This guide outlines the keys to building a truly effective and compliant supply chain network with the use of the latest technical advancements.

The Escalating Threat of Counterfeit Medicines: A Looming Global Crisis

Counterfeit medicines have emerged as a rapidly escalating threat, posing severe risks to patients, governments, and the pharmaceutical industry. The consequences of this alarming trend are dire, ranging from ineffective treatments, exacerbated health conditions, and even deaths to loss of trust in healthcare systems.

The Extent

According to the [recent data](#) unveiled by the nonprofit organization Pharmaceutical Security Institute (PSI), there is a remarkable escalation of the issue, with 6,615 pharmaceutical crime incidents documented in 2022. This figure marks a 38 percent increase from the previous year and the highest tally in a 20-year record.

Analyzing the regional distribution of counterfeit pharmaceutical seizures, North America took the lead with 2,442 cases, followed by the Asia Pacific (1,747), Latin America (770), the Near East (705), Eurasia (646), Europe (374), and Africa (187). This sequence primarily reflects the efficacy of law enforcement efforts and inspections by drug regulatory agencies across these regions.

The PSI considers that the number of fake pharmaceutical productions and distributions could be significantly greater than illustrated if we take into account the many unreported instances of counterfeit drugs that went unnoticed because of insufficient funding or regulatory inadequacies that may have similar implications for other nations.

The World Health Organization, which makes its own efforts to detect any threats to public health, also reveals a [troubling statistic](#): around 10 percent of medical products circulating in low- and middle-income countries are either substandard or falsified.

In sub-Saharan African nations, this figure may rise even higher, potentially reaching 19-50 percent according to the 2023 report titled 'Trafficking in Medical Products in the Sahel'. A span from 2017 to 2021 witnessed substantial international operations in West Africa, resulting in the seizure of at least 605 tons of diverse medical products, emphasizing the scope of the challenge at hand. Data from the United Nations Office on Drugs and Crime underscores a grim reality: nearly half a million lives are estimated to be claimed annually by counterfeit medicines in sub-

Saharan Africa. Among these, approximately 267,000 fatalities are linked to the consumption of falsified or substandard antimalarial medications. Additionally, another 169,271 lives are tragically connected to the use of counterfeit or substandard antibiotics, particularly concerning severe pneumonia cases in children.

Understanding Falsifications of Medical Products

There are four specific types of falsification of medical products, including tampering, theft, illegal diversion, and counterfeiting.

Counterfeit medicines, in their turn, come in various forms. While the [World Health Organization](#) defines substandard, falsified, and unregistered/unlicensed medical products, other institutes like the [ABDA](#) (Federal Union of German Associations of Pharmacists) go to a wider range of fake drugs which includes the following:

Copycat Counterfeits: These are exact replicas of legitimate medications, designed to deceive consumers. They may have similar packaging, branding, and labeling, making them difficult to distinguish from genuine products.

Substandard Medications: These medicines fall below quality standards due to poor manufacturing, storage, or transportation conditions. They might contain incorrect dosages, inactive ingredients, or contaminants, rendering them ineffective or potentially harmful.

Unapproved Formulations: Some counterfeit medicines contain active ingredients not listed on the label, putting patients at risk of adverse reactions and interactions with other medications.

Placebo Medications: These products contain no active ingredients, essentially offering no therapeutic effect. Patients might not experience any relief from their symptoms and could potentially delay seeking appropriate treatment.

Expired Drugs: Expired medications are often relabeled and sold as new, posing a significant health risk as their effectiveness could be compromised or they may have deteriorated over time.

Misbranded Medications: These involve products with incorrect or misleading labeling, such as incorrect dosage information, fake manufacturing dates, or unauthorized use of legitimate brands.

Recycled Medicines: These involve expired or discarded medications that are repackaged and sold as new. Patients unknowingly consume drugs that might be ineffective or harmful due to their deteriorated state.

Counterfeit Packaging: Even genuine medicines can be adulterated if they are packaged in counterfeit containers. Authentic medications might be removed from their original packaging and placed in substandard or fake packaging.

Counterfeiters may target not only prescription medications but also herbal supplements and dietary products. These counterfeits might contain harmful substances or none of the promised ingredients.

Reasons

The surge in counterfeit substandard pharmaceuticals is fueled by various factors, including the attraction of immense profits for illicit manufacturers, inadequate regulations, and the complexity of global supply chains.

Most often, counterfeiters are driven by the attraction of high profits with relatively low production costs. The pharmaceutical industry's lucrative nature makes it an attractive target for those seeking financial gain. On the other hand, inadequate regulatory enforcement, especially in certain regions, allows counterfeiters to operate with relative impunity. Gaps in oversight can lead to substandard or unregulated products entering the market. This is especially relevant to the regions with political instability or conflicts.

As the pharmaceutical supply chain is intricate, involving multiple parties such as manufacturers, distributors, wholesalers, and retailers, counterfeiters can exploit this to introduce fake products at various points. The absence of robust serialization and traceability mechanisms, as well as standardized and transparent data-sharing mechanisms in supply chains, makes it challenging to track products from manufacturer to patient, enabling counterfeit products to go undetected. And with globalization, even more intermediaries and cross-border transactions take

place creating more opportunities for falsified products to infiltrate the market.

Another contributing factor is the proliferation of online pharmacies, offering anonymity and accessibility to medicaments. This digital landscape provides criminals with a convenient avenue to sell fake or substandard drugs directly to consumers, often bypassing traditional supply chains.

In addition, counterfeiters leverage technological advancements to replicate packaging, labels, and security features, making it difficult for consumers and, sometimes, even professionals to distinguish genuine from fake products.

Consequences

The consequences are profound – consumers suffer from subpar treatments, drug resistance can develop, and vital medications become less reliable, putting vulnerable populations at risk.

Patients unknowingly consuming counterfeit medicines risk inadequate treatment for their conditions, leading to worsened symptoms, prolonged illnesses, life-threatening complications, or even deaths. The psychological toll is considerable as people who experience negative effects may become hesitant to trust future medications, undermining their overall well-being.

The ramifications of counterfeit drugs pose multifaceted challenges for governments as well. These include increased healthcare burdens due to ineffective treatments and higher medical expenditures, as well as undermined public trust in healthcare systems eroding the credibility of regulatory bodies. All these can further lead to strained relations with international trading partners, hinder investment in the pharmaceutical sector, and undermine economic growth.

For pharma companies, the consequences are also tough. Beyond the direct financial losses resulting from the proliferation of counterfeit products that undercut legitimate sales, they face reputational damage as their brands become associated with ineffective or even harmful medications. The effort required to identify and combat counterfeit products diverts resources from research and development, hindering innovation and potentially slowing down the introduction of new, life-saving drugs to the market. Moreover, the erosion of patient trust caused by counterfeit drugs can lead to reduced patient compliance and decreased loyalty to genuine products, impacting long-term profitability and market share.

Addressing this issue requires a multifaceted approach involving governments, pharmaceutical companies, regulatory bodies, and technology experts. Heightened regulations, stringent quality controls, and increased transparency in the supply chain are crucial steps.

Global Efforts To Combat Drug Counterfeits

Efforts to combat drug counterfeits are a global priority, involving a range of initiatives, partnerships, and strategies aimed at ensuring the safety and authenticity of medications.



Integrational Organizations

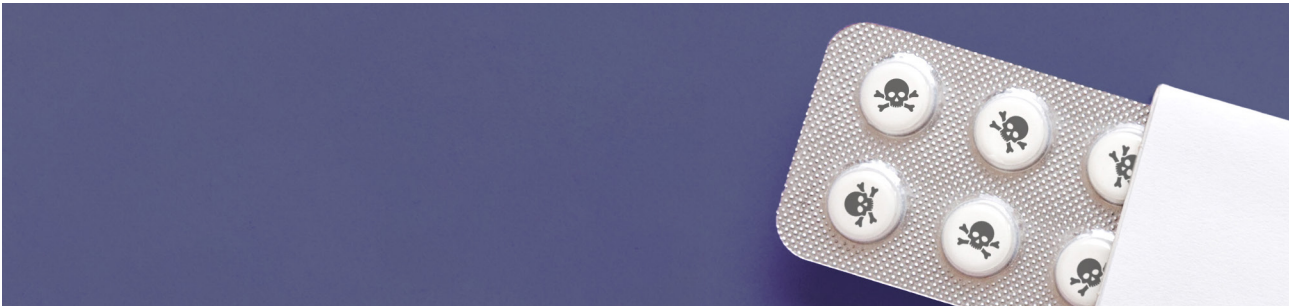
For example, the World Health Organization (WHO) leads international efforts through its “IMPACT” program ([International Medical Products Anti-Counterfeiting Taskforce](#)). IMPACT works to strengthen regulatory systems, enhance supply chain security, and raise public awareness about the risks of counterfeit medicines. It was launched in February 2006 and includes representatives from Interpol, Organization for Economic Co-operation and Development, World Customs Organization, World Intellectual Property Organization, World Trade Organization, International Federation of Pharmaceutical and Manufacturers’ Associations, International Generic Pharmaceuticals Alliance, World Self-medication Industry, Asociacion LatinoAmericana de Industrias Farmaceuticas, World Bank, European Commission, Council of Europe, Commonwealth Secretariat, ASEAN Secretariat, International Federation of Pharmaceutical Wholesalers, European Association of Pharmaceutical Full-line Wholesalers, International Pharmaceutical Federation, International Council of Nurses, World Medical Association, and Pharmaciens sans frontiers. IMPACT is comprised of five working groups that address the areas where action is needed. These are legislative and regulatory infrastructure; regulatory implementation; enforcement; technology; and communication.

Numerous [international initiatives](#) to combat the proliferation of counterfeit and unlawful drugs have been orchestrated by INTERPOL. For instance, in 2008 Operation Pangea was incepted with the participation of 8 countries. It was focused on curtailing the online trade of counterfeit and illegal medical products. This operation has progressively expanded to 123 countries in 2017 and resulted in 859 arrests globally and the confiscation of USD 14 million worth of potentially hazardous pharmaceuticals.

Apart from the worldwide Pangea initiatives, INTERPOL has also directed its attention towards several regional endeavors aimed at intercepting counterfeit pharmaceuticals. These initiatives encompass Operation Rainfall, concentrating on Asia (295 000 units seized amounting to \$122 400); Operation Qanoon, dedicated to the Middle East and North Africa (1.4 million units, \$1.5 million); and Operation Heera, concentrating on West Africa (95 800, \$3.8 million).

Under the purview of the World Customs Organization (WCO), an [Intellectual Property Rights \(IPR\), Health, and Safety Programme](#) is administered. This program is centered on strengthening capabilities through a multifaceted approach, which encompasses harmonizing the endeavors of WCO members and relevant international entities, collaborating closely with the private sector, and cultivating enforcement mechanisms. Part of this initiative involves enhancing capacities through accrediting experts, orchestrating seminars for customs officers at both regional and national levels, and conducting diagnostic missions. These missions encompass a comprehensive evaluation that spans the examination of national legislations, an assessment of risks inherent to specific countries, the engagement of rights holders, and collaboration with national competent authorities.

Collaborative initiatives, like the [Pharmaceutical Security Institute](#) (PSI), monitor and analyze data related to counterfeit incidents, helping identify trends and patterns.



Legislative measures

The [Council of Europe's Medicrime Convention](#) is the only international legal instrument specifically targeting counterfeit medical products and similar crimes. It facilitates cross-border cooperation among member states to combat the production and distribution of counterfeit medicines and provides the foundation for coordinated actions with and among global organizations like INTERPOL, Europol, UNODC, the WCO, and WHO. It has been ratified by 15 nations.

Besides this, more and more countries around the world are enacting and enforcing stringent legislation and penalties against counterfeiters, discouraging their involvement in the production and distribution of fake drugs.

[In 2012, Turkey pioneered the implementation of the comprehensive pharmaceutical track and trace system](#), becoming the global trailblazer in securing its domestic pharmaceutical supply chain. Following this successful endeavor, nations including Argentina and Saudi Arabia embarked on adopting similar solutions.

The [Falsified Medicines Directive](#) passed by the Council of the European Union and European Parliament in 2011 reflects the EU's commitment to ensuring the authenticity, safety, and efficacy of medicines within its member states, thereby safeguarding public health.

The Directive 2011/62/EU came into effect in January 2013 and was enforced in February 2019. It entails the following stipulations:

- The inclusion of a unique identifier and an anti-tampering device on the outer packaging of medicines.
- The introduction of a common, EU-wide logo intended to identify legal online pharmacies.
- The imposition of stricter regulations regarding the import of active pharmaceutical ingredients.
- Enhanced record-keeping obligations for wholesale distributors.

Pharmacies and other authorized entities responsible for supplying medicines to the public are mandated to authenticate products. This involves visually inspecting the anti-tamper device and conducting a verification and decommissioning scan "at the time of supplying it to the public".

Efforts are also underway in China and the United States to establish their own end-to-end pharmaceutical track and trace systems.

US Congress passed the Drug Quality and Security Act (DQSA) on November 27, 2013.

Title II of the DQSA, known as the Drug Supply Chain Security Act (DSCSA), delineates measures to establish interoperable, electronic product tracing at the package level. This initiative aims to efficiently identify and trace specific prescription drugs throughout their distribution within the United States.

The DSCSA requires trading partners to provide specific transaction information, transaction history, and transaction statements for each sale and distribution of prescription drugs.

Manufacturers and repackagers are required to affix a unique product identifier to each package of prescription drugs, allowing verification of the authenticity of the product.

The DSCSA also outlines procedures for identifying, quarantining, investigating, and reporting suspect or illegitimate products within the supply chain.

Wholesale distributors and third-party logistics providers must be licensed by the state or federal government, and licensure information must be reported annually to the FDA.

The DQSA establishes a national database for drug listings, enabling the accurate identification of drugs and facilitating tracking and tracing efforts.

In addition, DQSA increases the penalties for violations related to counterfeit drugs and illegal distribution, deterring unlawful activities in the pharmaceutical supply chain. Upon confirming the illegitimacy of a product, manufacturers, repackagers, wholesale distributors, and dispensers have to promptly notify the FDA within a 24-hour timeframe. countries, the engagement of rights holders, and collaboration with national competent authorities.

Collaborative initiatives, like the [Pharmaceutical Security Institute](#) (PSI), monitor and analyze data related to counterfeit incidents, helping identify trends and patterns.



Outcomes

Such regulations help enhance patient safety by reducing the risk of counterfeit, substandard, or falsified medicines entering the legitimate supply chain. However, their implementation requires close collaboration between pharmaceutical manufacturers, wholesalers, pharmacists, and other stakeholders involved in the supply chain. Non-compliance, on the other hand, can put at risk healthcare ecosystem stability. For example, if a pharmaceutical manufacturer cannot provide unit-level serialized products to its distributors, no one along the supply chain can legally move it to the next step. If the distributor is unable to provide the pharmacy with electronic tracing data, the pharmacy cannot legally receive the product, and dispense it to the patient.

What is Supply Chain Traceability And How To Achieve It

As you can see, at the center of any anti-counterfeit effort there is an ability to track and localize each particular drug throughout the supply chain.

The specific requirements of traceability laws may vary depending on the country or region, but they generally involve the following aspects

Serialization

Pharmaceutical companies are required to assign a unique serial number or identifier to each individual unit of their products, such as bottles or packages. This enables tracking and tracing them throughout the supply chain.

GS1, a global standards organization, provides guidelines for serialization in the pharmaceutical industry to facilitate the implementation of traceability solutions that comply with regulatory requirements and industry best practices. These guidelines are designed to ensure the unique identification and tracking of pharmaceutical products using GS1 standards. Below are some key aspects covered in GS1 serialization guidelines:

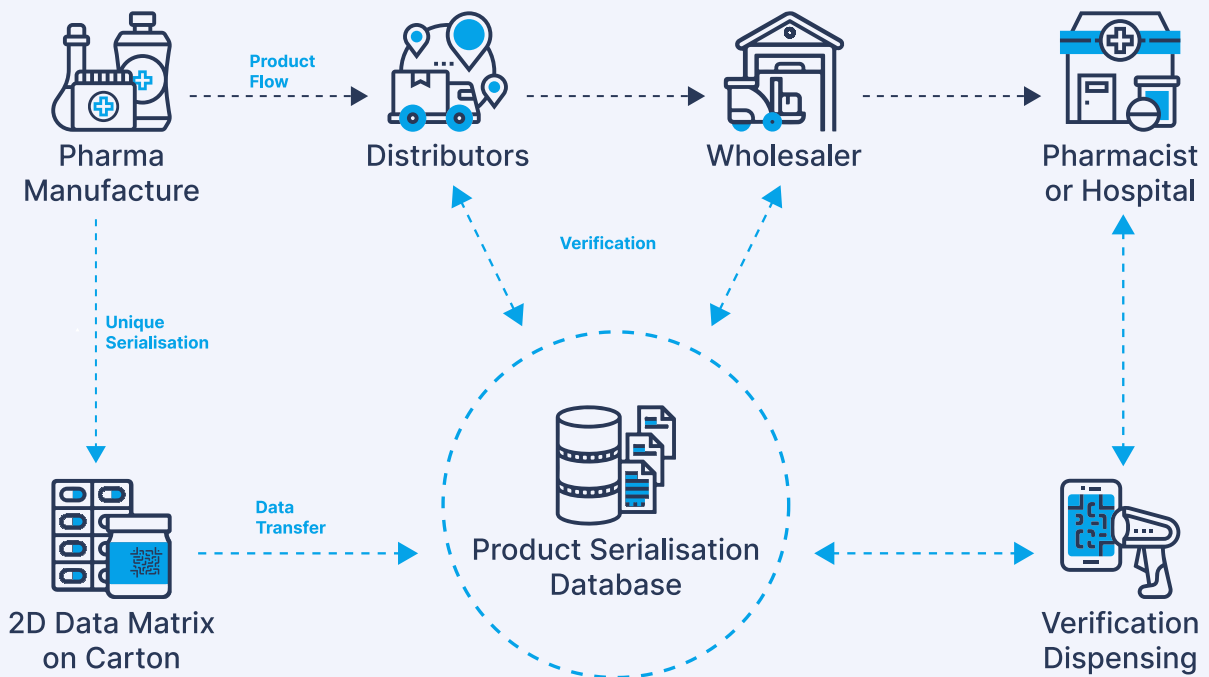
- GS1 serialization guidelines recommend using GS1 Identification Keys, such as Global Trade Item Numbers (GTINs) and Serial Shipping Container Codes (SSCCs), to uniquely identify pharmaceutical products and packaging levels. GTINs are used to identify product units, while SSCCs are used to identify shipping containers or pallets.
- GS1 provides guidelines for structuring the serialized data, including the Global Trade Item Number (GTIN), batch/lot number, expiry date, and serial number. This structured data is encoded in a two-dimensional barcode (e.g., GS1 DataMatrix) placed on the product's packaging.
- GS1 recommends using 2D barcodes, such as GS1 DataMatrix or GS1 QR Code, to encode the serialized data on pharmaceutical product packaging. These barcodes are capable of holding the required data elements in a compact format.
- The guidelines address data exchange formats and protocols to facilitate the seamless exchange of serialized data between trading partners, such as manufacturers, wholesalers, and pharmacies. This interoperability is essential for ensuring end-to-end traceability across the supply chain.
- GS1 provides guidelines for product aggregation, which involves associating the unique serial numbers of individual product units with higher-level packaging, such as cartons and cases.

An illustration of this is the consolidation of individual packs into larger containers, commonly known as multi-packs. In such instances, only the multi-pack receives a serial number. The smaller packaging units within it are not required to undergo serialization since the multi-pack functions as an independent sales entity with its distinct product identification.

- GS1 guidelines cover the processes for verifying the authenticity of serialized products at various

points in the supply chain. Additionally, they address the decommissioning of serial numbers after the product is dispensed to the end consumer, preventing duplicate use of the same identifier.

- GS1 requires secure and efficient data management systems to handle the large volumes of serialized data generated throughout the supply chain. This includes data storage, retrieval, and data-sharing mechanisms.



Data Capture

Companies need to capture relevant data associated with each serialized unit, including information about the product, batch number, manufacturing date, expiry date, and other details. This data is typically stored in a centralized database or system.

In fact, pharmaceutical firms have to create countless serial numbers, encode them, imprint them on the packaging, and maintain their storage and management over extended periods. That's why without proper systems in place all these may quickly come out of order.

Data Exchange

The captured data needs to be shared with regulatory authorities, trading partners, and other stakeholders involved in the supply chain. This facilitates effective tracking and tracing of products, enabling prompt response in case of product recalls, quality issues, or suspected counterfeit incidents.

Supply Chain Integration

Pharma companies must integrate their systems and processes with their suppliers, distributors, and other partners in the supply chain. This integration enables seamless data exchange and facilitates end-to-end traceability.



Verification and Authentication

Traceability laws often require the implementation of mechanisms to verify the authenticity of pharmaceutical products, such as tamper-evident packaging or anti-counterfeiting technologies.

The European Medicines Verification Organisation (EMVO) is responsible for overseeing the implementation and operation of the European Medicines Verification System (EMVS) across EU member states. It coordinates various stakeholders, including manufacturers, wholesalers, and pharmacies, to ensure smooth functioning.

Other reasons to ensure pharma supply chain transparency

Beyond regulatory compliance and the fight against counterfeit products, ensuring supply chain transparency is paramount for building trust, driving innovation, and fostering sustainability. Transparent supply chains inspire consumer confidence by showcasing a commitment to product safety and ethical sourcing, ultimately enhancing brand reputation. Moreover, they serve as fertile ground for innovation, enabling data-driven decision-making, optimized processes, and rapid responses to market changes.

Here are some specific considerations:

Quality control

By maintaining transparency in the supply chain, pharmaceutical companies can ensure the quality and safety of their products. They can track and monitor the sourcing of raw materials, manufacturing processes, and distribution channels, allowing them to identify and address any potential issues that could compromise product quality or integrity.

Corporate ethics

Transparency in the pharmaceutical supply chain aligns with ethical principles and corporate social responsibility. Patients and healthcare providers increasingly value transparency and accountability from pharmaceutical companies. It helps build trust among stakeholders and ensures that medications are sourced and produced responsibly, without exploiting labor or engaging in unethical practices.

Risk mitigation

Supply chain transparency allows pharmaceutical companies to identify and mitigate risks more effectively. They can proactively monitor potential disruptions, such as shortages of raw materials or manufacturing delays, and take corrective actions to minimize their impact. Transparent supply chains also help companies respond to unexpected events, such as natural disasters or public health emergencies, by facilitating faster and more efficient distribution of essential medications.

Reputation and brand value

Supply chain transparency can positively impact a pharmaceutical company's reputation and brand value.

Companies that prioritize transparency and provide visibility into their supply chains demonstrate their commitment to patient safety, quality, and ethical business practices.

This can enhance their brand image, attract more customers, and differentiate them from competitors.

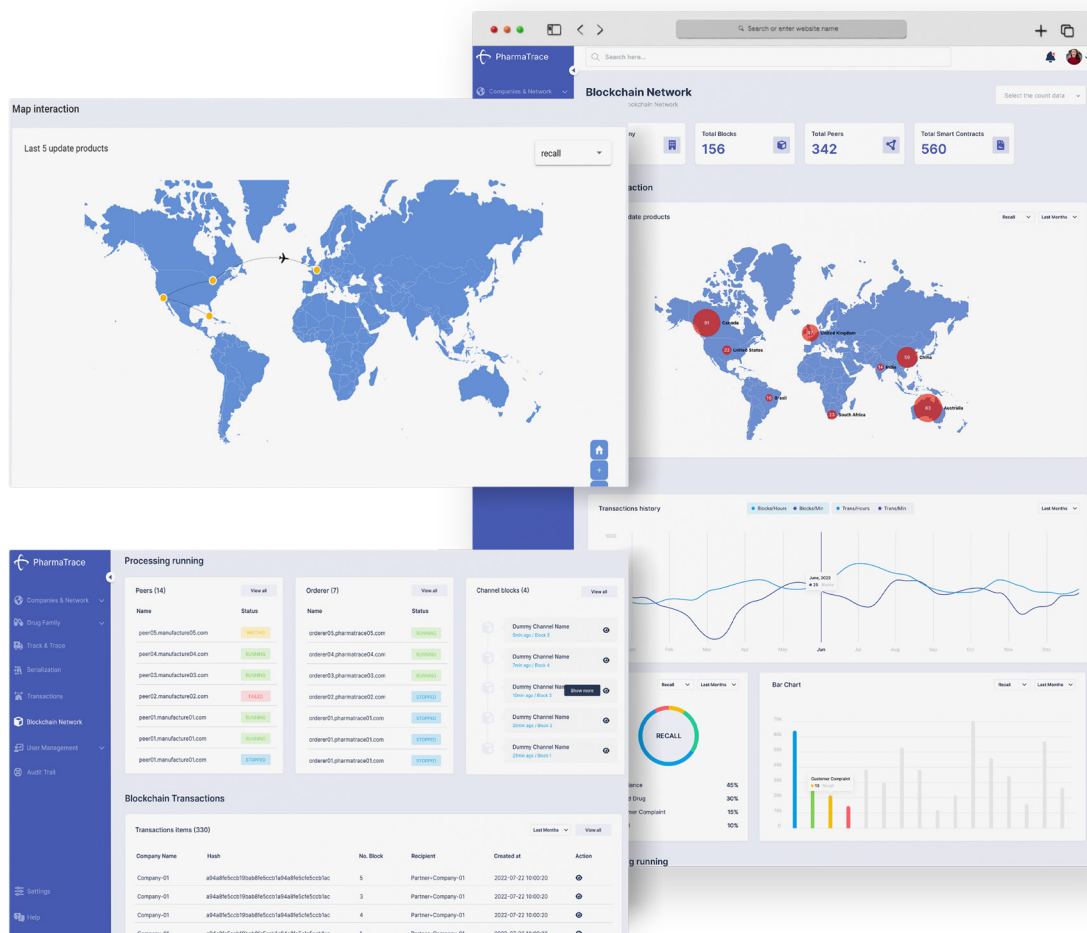
In summary, ensuring supply chain transparency not only helps to meet regulatory requirements and safeguards against counterfeits but also unlocks a multitude of advantages that propel businesses toward a more ethical, competitive, and sustainable future. It is also proven to mitigate supply chain risks and optimize operational costs, but its effective implementation requires strong alignment between business and supply chain strategy, as well as the true commitment of the company's executives and service providers.



PharmaTrace: Tailored Blockchain-Based Solutions for Pharma Supply Chain Traceability

With a strong commitment to leveraging blockchain technology, PharmaTrace is dedicated to providing all the required services for the pharma companies' supply chain data management while creating innovative solutions that enhance transparency, security, and collaboration within healthcare networks.

Our tailored and fully scalable offerings empower industry stakeholders to streamline their operations, adhere to regulatory standards, beat competition, and foster seamless interactions with other participants in the ecosystem.



Serial Number Management

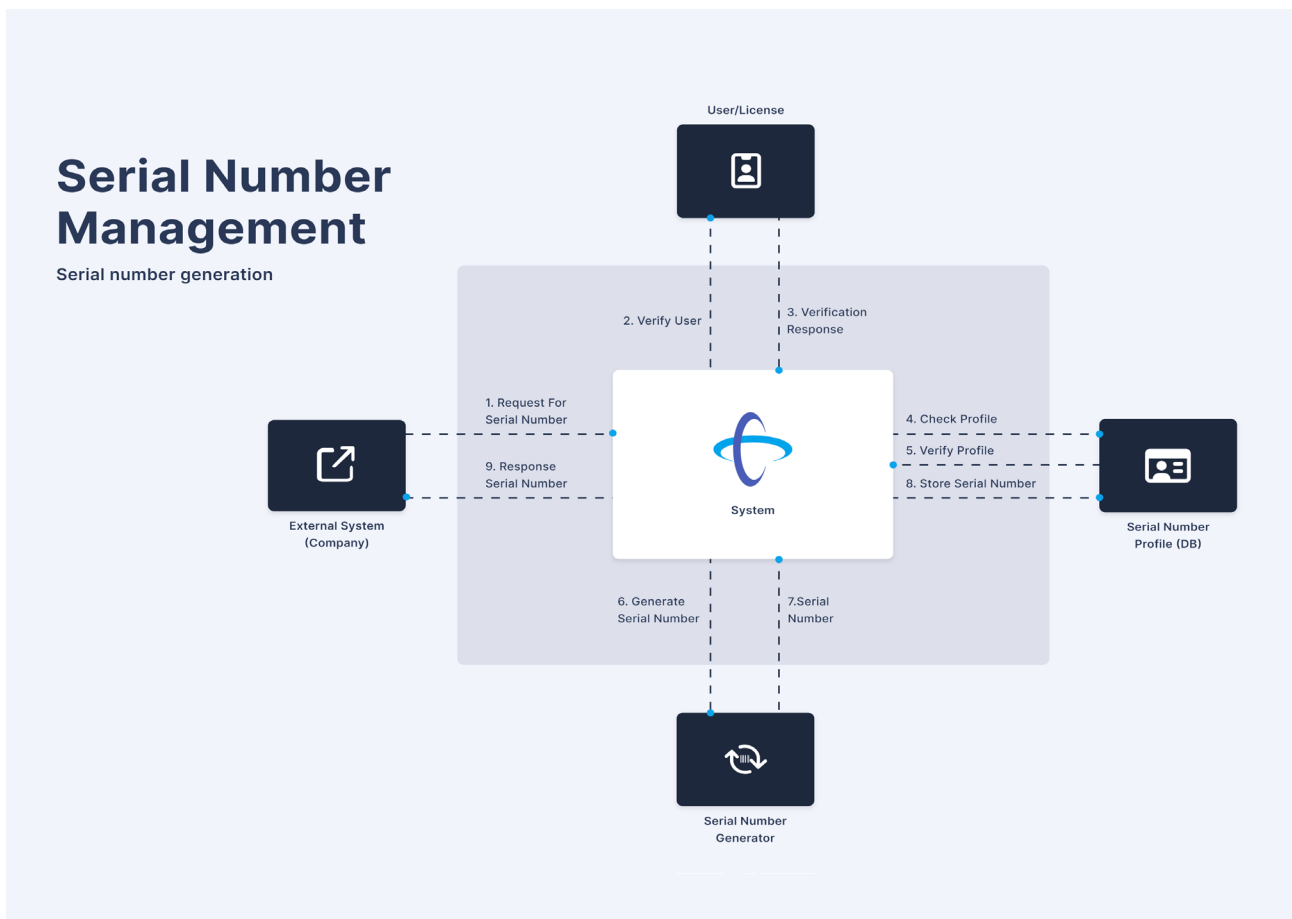
Serial number management is the linchpin of pharmaceutical supply chain security, empowering stakeholders to track, verify, and maintain the integrity of critical medications, ultimately enhancing patient safety and bolstering industry confidence. However, different approaches to this may be applied by the companies. At PharmaTrace we offer random, GDTI, and SSCC, serial number management options that will make it easier to cooperate within custom networks as well as adhere to stringent regulatory instructions.

PharmaTrace’s Serial Number Management module encompasses the storage, creation, reception, and issuance of serial numbers, or EPCs (electronic product codes). Its core function lies in ensuring the uniqueness of serial numbers for a specific customer/product combination.

Within PharmaTrace, two distinct categories of data are processed: serial number data, which involves the allocation of unique identifiers to various pharmaceutical packaging levels, and notification data, which comprises serial numbers and pertinent business event information.

Random Serial Number Profiles

While the structure and standards for notification data typically adhere to industry norms or protocol definitions, serial number data, often referred to as provisioning data, does not strictly follow established standards or protocols, making its exchange in system-to-system transactions more intricate.



To address this, PharmaTrace offers extensive support for generating randomized serial numbers, leveraging configurable characteristics within random numbers configurations and integrated XSLT capabilities. Users can manually configure these numbers when first accessing the system, set up number parameters, and upload list-based serial numbers (those received via email or USB key).

This versatile approach accommodates various serial number generation methods to meet specific business requirements, including stringent regulatory demands like those outlined in Article 4 of the European Union's Delegated Regulation (EU) 2016/161, which mandates that serial numbers should be virtually impossible to guess and possess specific randomization criteria. These criteria include an equal distribution of substrings, independence among substrings, and resistance to algorithmic deciphering, thereby upholding robust security standards and data integrity.

Meanwhile, serial number randomization is performed in compliance with strict requirements set by Article 4 of the EUDR which mandates that the unique identifier should comprise a numeric or alphanumeric sequence, with a maximum length of 20 characters, generated through either a deterministic or non-deterministic randomization algorithm ('serial number'). The probability of guessing the serial number must be extremely low, less than one in ten thousand. Moreover, when dealing with a substantial set of randomized serial numbers for a product, the randomization substrings must exhibit equal distribution, be independent of one another, and not employ easily discernible algorithms, even when some serials or subsets are known.

GDTI

The Global Document Type Identifier (GDTI) is a standardized coding system designed to uniquely identify various document types critical to regulatory compliance and efficient supply chain operations. Each GDTI code serves as a digital fingerprint, distinguishing documents such as labeling, package inserts, or certificates of analysis. By assigning these unique identifiers to vital documents, the pharmaceutical sector can streamline documentation management, enhance traceability, and ensure adherence to rigorous regulatory requirements, ultimately bolstering transparency and safety within the industry's complex ecosystem.

The GDTI ranges configured within PharmaTrace serve as the Identification Key for document tracking. Such an identifier combines the document type with an optional serial number. To create a new number range, one needs only to specify the values for the GDTI Number Range. It is also possible to select the GDTI definition from the predefined list to view or modify the values associated with that particular number range.

SSCC

Each unique SSCC (Serial Shipping Container Code) contains essential information about a specific shipping container or pallet, including product details, batch information, and destination data. This level of granularity ensures that pharmaceutical companies can maintain the highest standards of quality, security, and regulatory compliance while optimizing their logistics and distribution processes. In other words, this helps to safeguard the integrity of pharmaceutical products from the manufacturer to the end-user.

SSCCs are assigned and verified within the PharmaTrace system according to the GS1 standards. The GS1 Application Identifier "00" is a critical component of SSCC barcodes as it signals that the encoded data pertains to these unique logistic unit identifiers, facilitating their accurate and standardized interpretation across various systems and applications.

Transaction Module

In the PharmaTrace system, a transaction represents a sequence of operations executed in a predefined order to achieve a specific outcome. For instance, in the context of serialization, they encompass tasks like data entry, validation, storage, retrieval, and reporting. The fundamental purpose of a transaction is to ensure the accurate and consistent execution of these actions while promptly detecting and rectifying any errors or inconsistencies that may arise. Transactions can range from single, user-initiated actions to automated processes triggered by the software.

To uphold data integrity and result accuracy, we have advanced techniques such as transaction logging, rollback mechanisms, and error handling in place. These mechanisms ensure the software’s reliability and effectiveness even when confronted with dynamic conditions and unexpected events.

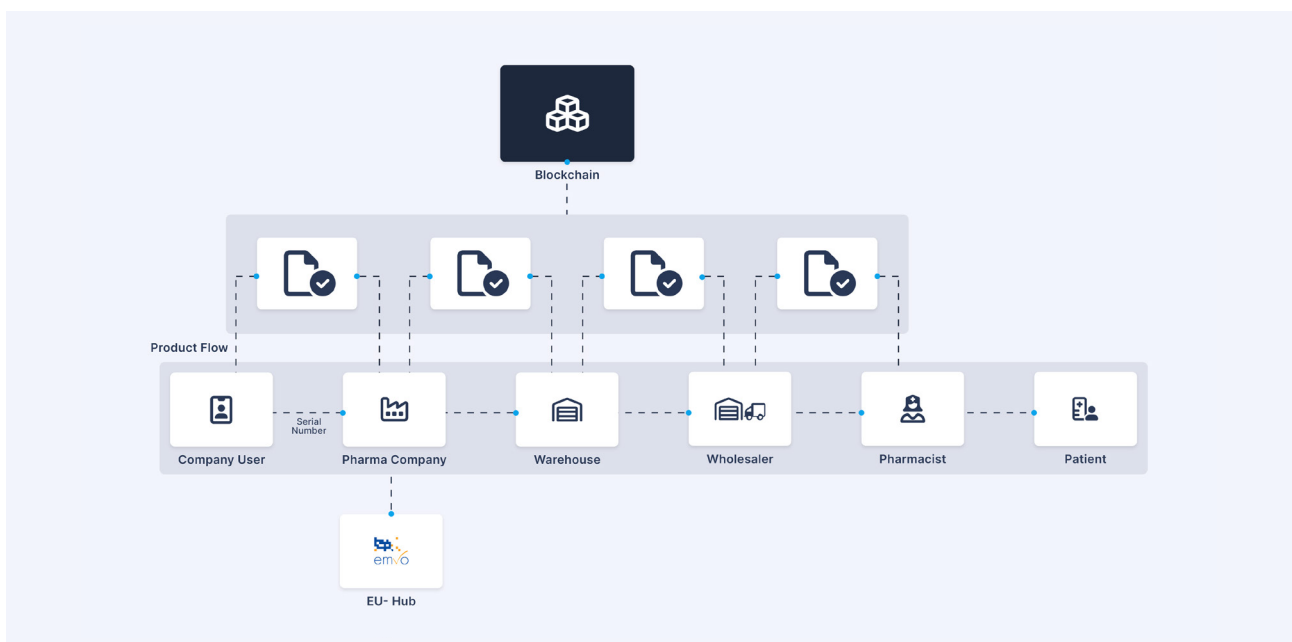
The Transaction Module in Pharmatrace is divided into four sub-modules: Serial Number Transaction, Lot/Batch Transaction, Product Recall Transaction, and Product Shortage Transaction.

All of them collectively empower our platform to efficiently manage serialization-related tasks, product recalls, and shortages, promoting data accuracy, compliance, and effective supply chain management.

Serial Number Transaction

The Serial Number Transaction sub-module is pivotal for ensuring product traceability and authenticity. It encompasses multiple critical functions to ensure the transparency of the serial number transaction:

- Serial Number Assignment - Allows users to assign unique serial numbers to each product during production.
- Serial Number Tracking - Tracks the location and status of each serial number, including usage, sales, returns, or recalls.
- Serial Number Validation - Ensures the validity of each serial number, preventing fraudulent or incorrect use.



In essence, the Serial Number Transaction sub-module forms the cornerstone of pharmaceutical serialization, guaranteeing the integrity, security, and compliance of each product as it moves through the intricate web of pharmaceutical distribution.

Lot/Batch Transaction

The Lot/Batch Transaction sub-module plays a pivotal role in managing the production and distribution of products in distinct lots or batches. It facilitates the creation and labeling of new lots or batches, ensuring precise tracking of each unit's location and status throughout the supply chain, including sales, returns, or recalls.

Moreover, it meticulously validates the compliance of each lot or batch with essential quality standards, contributing to the pharmaceutical industry's commitment to product quality and patient safety.

With the Lot/Batch Transaction sub-module, pharmaceutical companies can maintain tight control over their production processes and confidently address any quality-related issues that may arise, thus upholding their reputation for producing safe and effective medications.

Product Recall Transaction

Product recall in the pharmaceutical industry is a critical process designed to address the identification and removal of pharmaceutical products from the market due to safety concerns, defects, or non-compliance with regulatory standards. It involves multiple stages, including the initiation of a recall, tracking the progress of the recall, and notifying relevant stakeholders, such as healthcare providers and patients, about the recall and the steps to return or replace the affected products.

Product recalls are essential for maintaining patient safety, regulatory compliance, and public trust in the pharmaceutical industry, and they require meticulous planning, execution, and communication to ensure a swift and effective response to potential risks associated with pharmaceutical products.

In the PharmaTrace system, the recall transaction sub-module encompasses all the required operations:

- Recall Initiation - Allows users to initiate recalls for specific products or batches.
- Recall Tracking - Monitors the recall's progress, including returned products and those still in circulation.
- Recall Notification - Sends notifications to customers, retailers, and stakeholders regarding the recall and provides return instructions.

Product Shortage Transaction

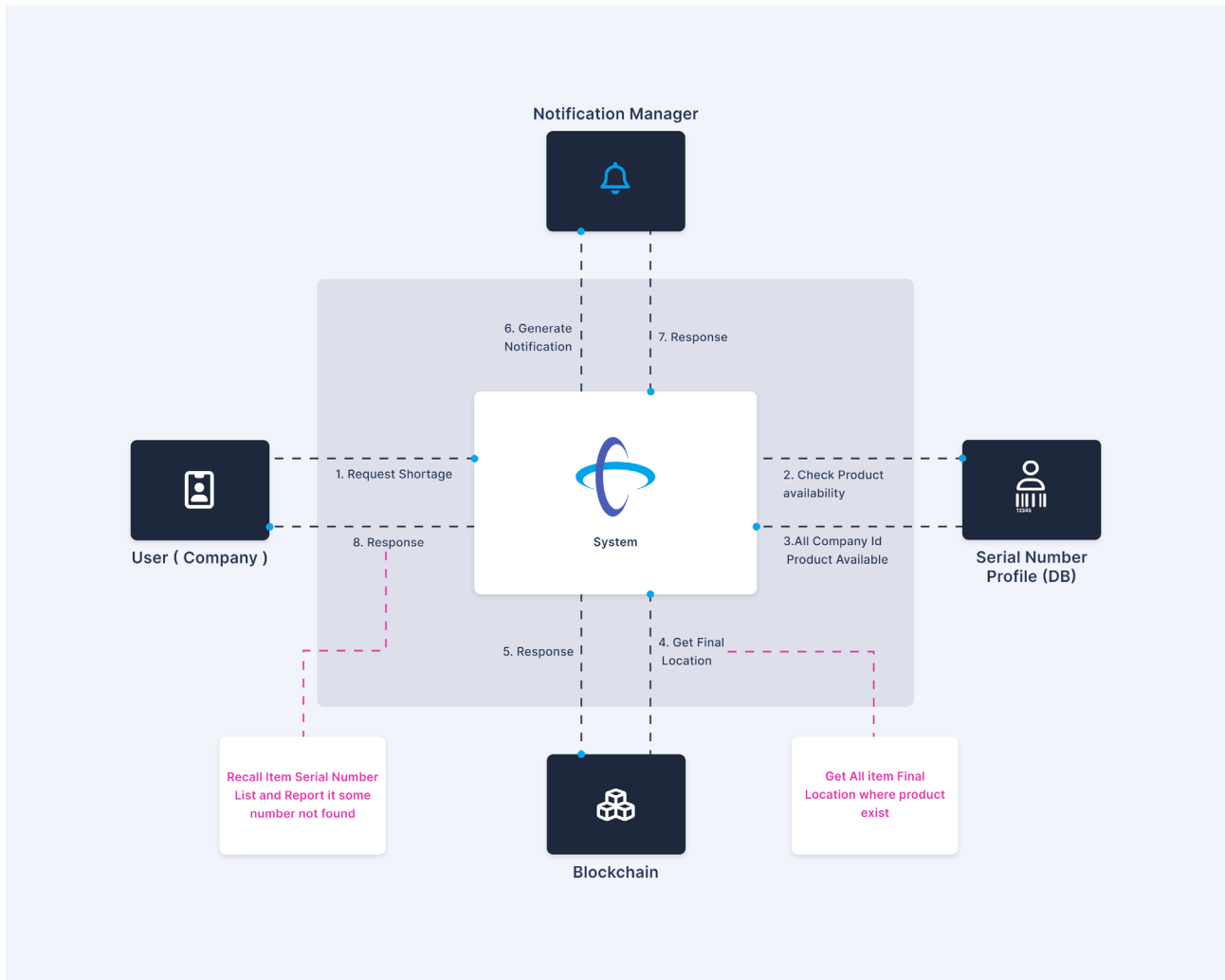
Product shortages in the pharmaceutical industry represent a critical challenge affecting patient care and the supply chain. They occur when the demand for essential medications surpasses the available supply, leading to delayed or restricted access to vital drugs.

Factors contributing to shortages can range from manufacturing disruptions and quality control issues to regulatory hurdles. The consequences of such shortages are far-reaching, impacting patient health and safety, healthcare providers' ability to deliver care, and pharmaceutical companies' reputations.

Effective management of product shortages is essential, involving timely communication, allocation strategies, and collaboration among stakeholders to ensure that patients continue to receive the medications they need without compromising their well-being.

PharmaTrace's Product Shortage Transaction sub-module includes the following functionality:

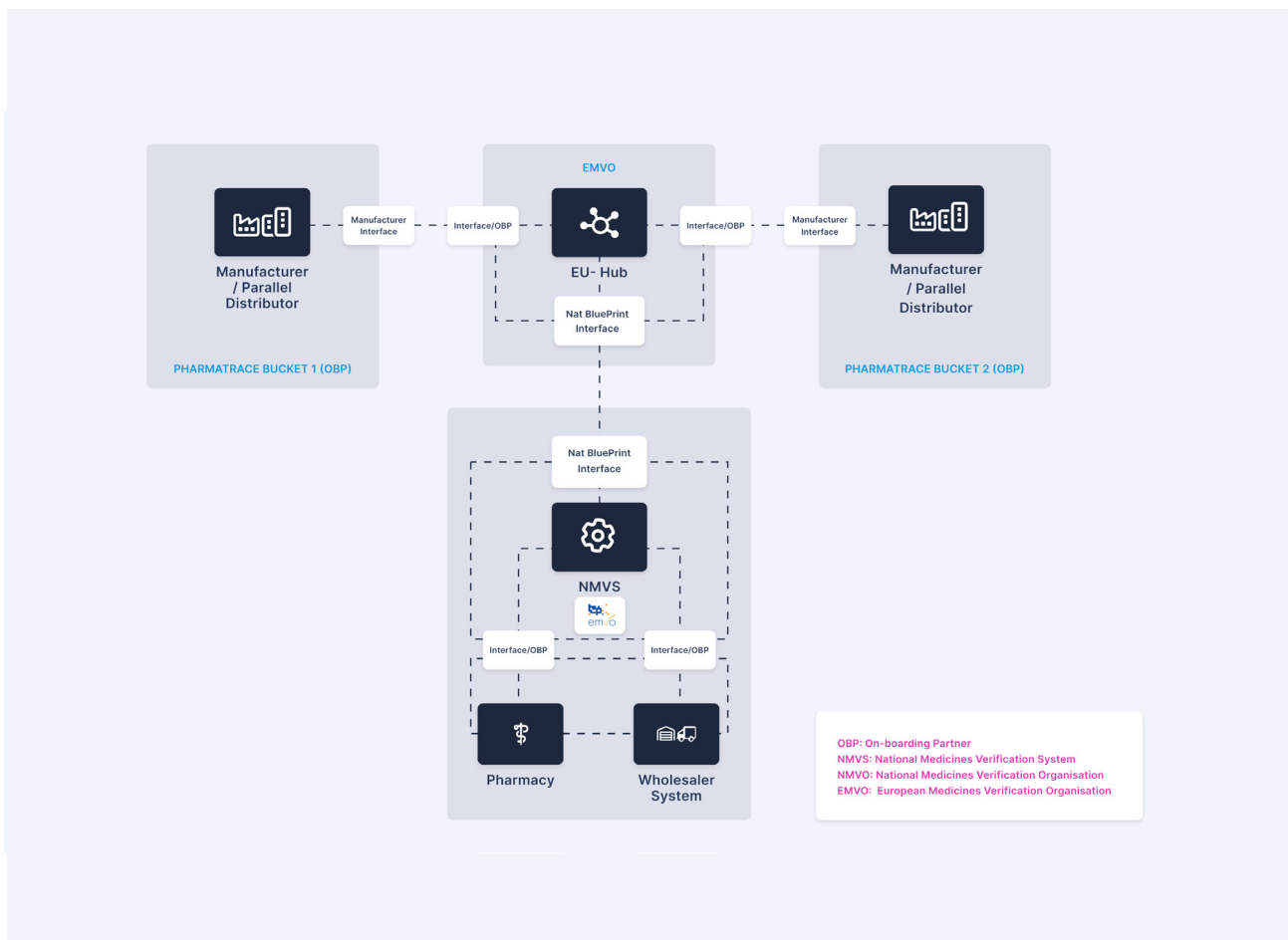
- ▶ Shortage Identification - Enables users to identify products in short supply and prioritize orders for these items.
- ▶ Shortage Notification - Notifies customers, retailers, and stakeholders about product shortages and provides updates on product availability.
- ▶ Shortage Management - Assists users in allocating limited product supplies fairly and equitably to customers and retailers.



Reporting Module

Reporting plays a pivotal role in the serialization process, aligning with EU regulations that mandate pharmaceutical companies to adhere to serialization standards. This entails assigning a unique Global Trade Item Number (GTIN) to their products and submitting these serial numbers to the Central Authority, EMVO (European Medicines Verification Organisation). These records serve as a crucial resource for verifying the authenticity of pharmaceutical products in the future, ensuring compliance with stringent regulatory requirements.

The Reporting Module within the PharmaTrace system is a vital component as it plays a pivotal role in collecting, aggregating, and analyzing data related to various pharmaceutical processes, including serialization, track and trace, quality control, and compliance. Through this module, pharmaceutical companies can generate comprehensive reports that provide critical insights into their operations, ensuring adherence to regulatory standards, identifying trends, and enhancing supply chain efficiency.



Blockchain in Pharma Supply Chain Management

At PharmaTrace, we found out that cutting-edge technologies like blockchain, which ensures traceability and authenticity, could prove instrumental in curbing the counterfeit medicine crisis, meeting regulatory requirements, and addressing all the issues mentioned in the sections above. With its unique characteristics, blockchain offers a secure, transparent, and efficient solution for tracking and verifying pharmaceutical products as they move from manufacturer to patient. Let's explore its fundamentals in the pharmaceutical sector, its defining characteristics, and the multitude of advantages our blockchain-based system brings to this critical industry.

Blockchain Defined

At its core, blockchain is a decentralized and immutable digital ledger. It comprises a chain of blocks, each containing a set of transactions. These blocks are linked together in chronological order, forming a tamper-proof chain. Once data is recorded on the blockchain, it cannot be altered, ensuring data integrity and trust among participants.

Characteristics of Blockchain

Before discussing the benefits of Blockchain for the pharma supply chain, let's focus on its main features and how they make it a revolutionary and highly desirable platform for various applications.

Decentralization

Blockchain operates on a decentralized network of computers, eliminating the need for intermediaries. This decentralized structure enhances security and reduces the risk of a single point of failure.

Immutability

Data recorded on the blockchain is irreversible. Once a transaction is confirmed, it is stored in a block, making it impossible to alter or delete. This characteristic guarantees data integrity.

Security

Blockchain uses advanced cryptographic techniques to secure data. Each participant has a private key, and transactions are validated through consensus mechanisms, making it extremely secure.

Transparency

Blockchain offers real-time visibility into transactions for all authorized participants. This transparency is particularly valuable in the pharmaceutical supply chain, where stakeholders can track the journey of each product.

Efficiency

Smart contracts, self-executing code on the blockchain, automating processes and enforcing predefined rules, streamlining operations, and reducing errors.

Advantages of the Blockchain Technology Applied By PharmaTrace

PharmaTrace leverages blockchain technology to revolutionize pharmaceutical supply chain management, offering a multitude of advantages. By utilizing the inherent transparency and immutability of blockchain, PharmaTrace enhances traceability and accountability throughout the entire supply chain. It ensures that every pharmaceutical product's journey, from manufacturer to end-user, is meticulously recorded and verified, reducing the risk of counterfeits and errors. Moreover, blockchain's smart contracts automate and streamline processes such as serialization, track and trace, drug recalls, and regulatory compliance, minimizing human error and improving efficiency. This innovative approach not only bolsters patient safety and regulatory adherence but also drives cost savings and fosters trust among stakeholders in the pharmaceutical ecosystem.

Here are some of its critical benefits in more detail:

Traceability

As each product is assigned a unique identifier (those could be aligned with the drug serial number, see Serialization), all the stakeholders can easily track its journey through the supply chain, from manufacturing to distribution.

Regulatory Compliance

Blockchain simplifies compliance by providing real-time access to data. Ensuring adherence to regulatory standards, and sending predefined alerts to the involved parties.

Counterfeit Prevention

Blockchain's transparency and immutability make it exceedingly difficult for counterfeit drugs to enter the supply chain. This protects patient safety and brand reputation.

Data Security

Sensitive information is safeguarded through blockchain's robust security measures. Access is restricted to authorized parties, reducing the risk of data breaches.

Efficiency and Cost Reduction

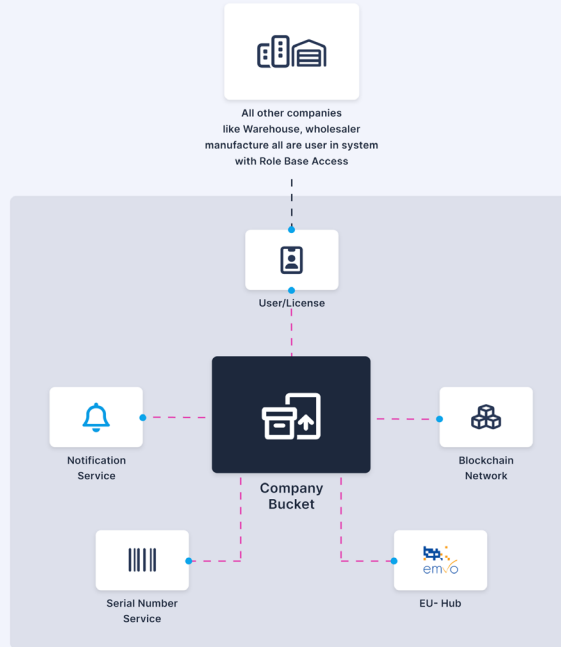
Smart contracts automate processes like compliance checks, reducing administrative overhead and speeding up transactions.

Patient-Centric Care

Patients can access verified information about their medications' origins and authenticity, promoting trust and patient-centric care.

As you can see, embracing blockchain can enhance patient safety, streamline operations, and ensure compliance with evolving regulations in this critical industry.

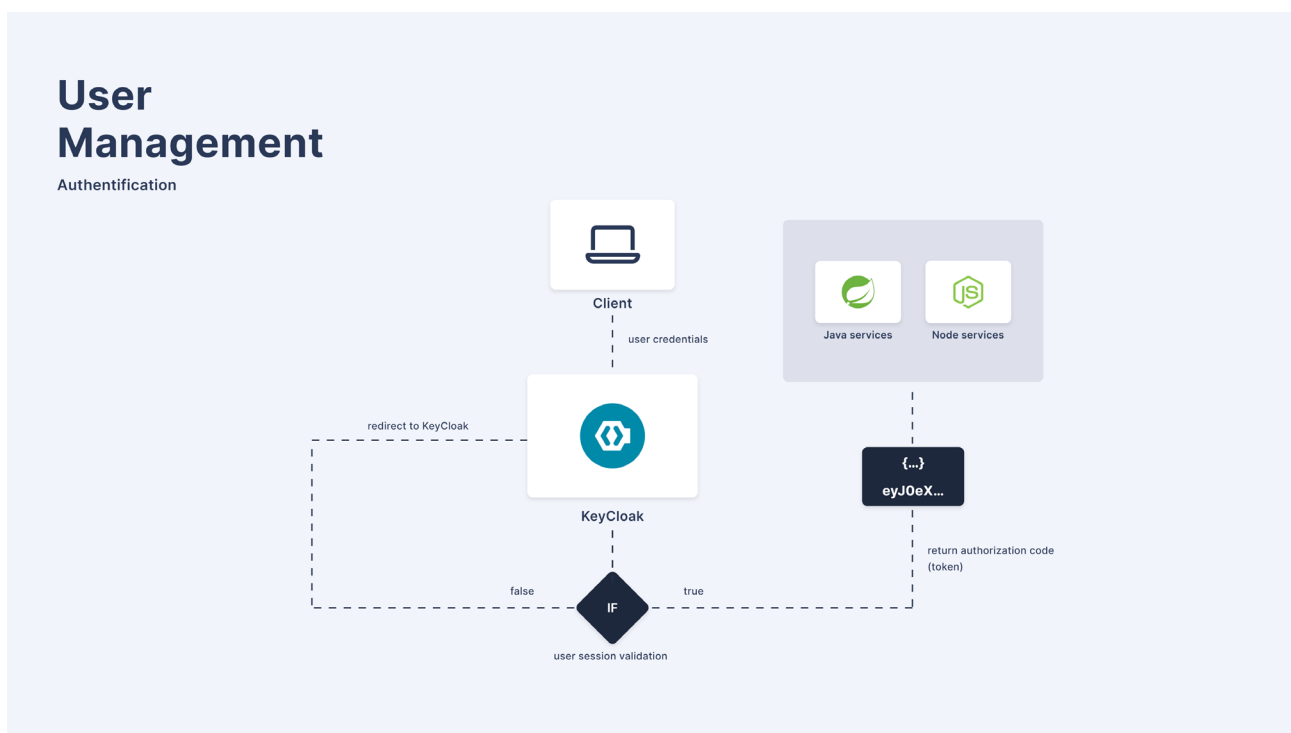
Company and Network



User Management

In the PharmaTrace system, every entity is allocated a distinct role, and access permissions are determined based on these roles. User identification is based on the username, and multiple user IDs can be generated under a single email address, with the username distinguishing accounts across the PharmaTrace platform. Admin privileges encompass the ability to modify existing accounts for streamlined management.

A unique identifier is established through blockchain integration to ensure uniqueness. Each user account is associated with a specific company, preventing multiple accounts linked to one company.



User Journey

The user journey within Pharmatrace's software is a meticulously structured process designed to seamlessly guide clients through every phase of their pharmaceutical supply chain management solution.

Onboarding

Collection of Customer Demands and Data: The user journey begins with a thorough understanding of the customer's needs and requirements. Pharmatrace collaborates closely with clients to collect vital data, ensuring a clear and comprehensive vision of the project.

Developing Technical Requirements: With customer demands in hand, the process moves to defining the technical specifications. Pharmatrace's expert team works diligently to create a precise roadmap for the project, aligning it with the client's objectives.

Contracting IT Team: Once technical requirements are established, the IT team is engaged. Contracts are finalized, and the project officially kicks off.

Beta-Version

Development of MVP: The journey advances to the development stage, where the Minimum Viable Product (MVP) is crafted. PharmaTrace's development team and contractors work diligently to create a functional prototype that showcases key features and functionalities.

Adding Users and Configuring Profiles: With the MVP in place, users are added to the platform, and their profiles are configured. This stage allows for a real-world simulation of the software, providing valuable insights for further refinement.

Testing In-House: Rigorous in-house testing commences to identify and rectify any issues or bugs. PharmaTrace ensures that the platform meets its quality standards before customer engagement.

Testing by the Customer: The beta version is then handed over to the customer for their evaluation. Customer testing allows for firsthand feedback, enabling fine-tuning of the software to align it with specific user needs.

Integrating Improvements (If Necessary): Based on customer feedback, necessary improvements and enhancements are integrated into the software. Pharmatrace remains agile, ensuring that the product meets evolving requirements.

Product

Deployment of Final Version: With improvements incorporated, the final version of the software is ready for deployment. PharmaTrace ensures a smooth and efficient transition from the beta version to the product release.

Instructing the Customer: As the product is deployed, PharmaTrace provides comprehensive training and guidance to the customer. This step ensures that users are proficient in utilizing the platform effectively.

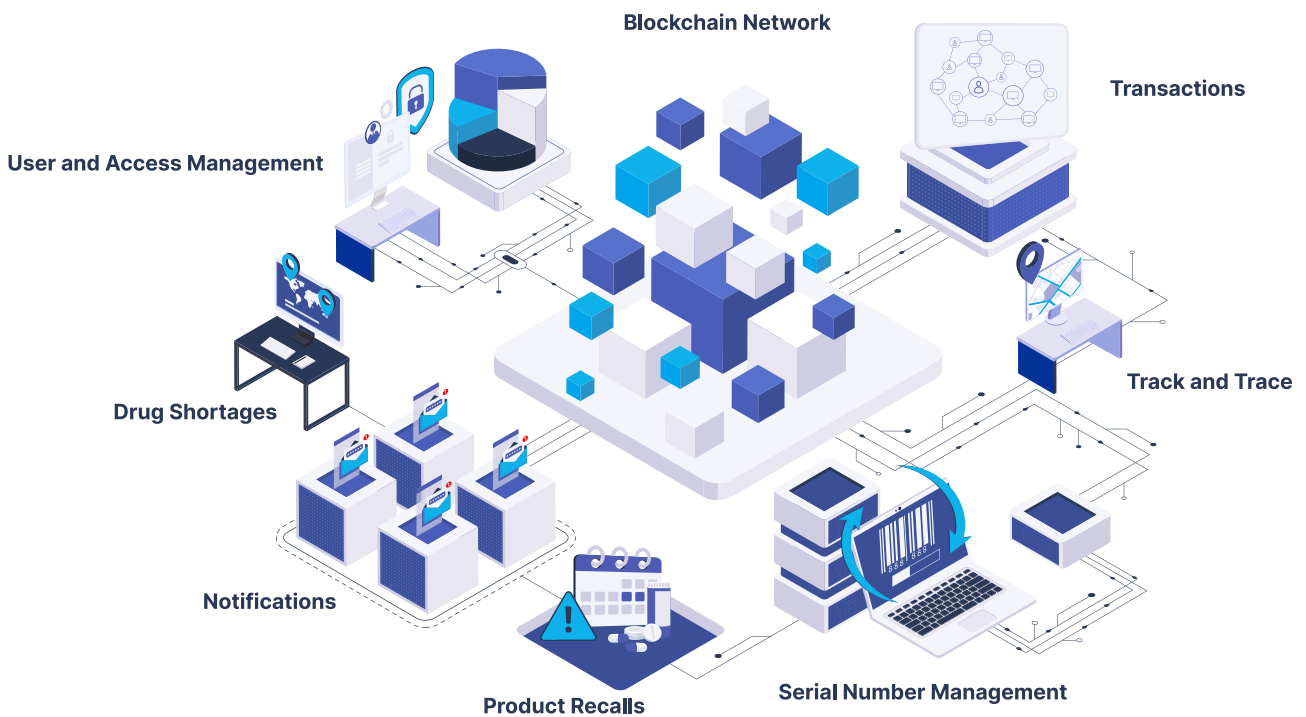
Customer Lifelong Support: The journey doesn't end with deployment. PharmaTrace is committed to offering lifelong support and assisting customers with any issues, updates, or evolving needs that may arise. The

relationship is ongoing, ensuring the continuous success of the pharmaceutical supply chain management solution.

This journey is marked by collaboration, refinement, and ongoing commitment to ensure that the software consistently aligns with user demands and delivers optimal value throughout its lifecycle.

The solutions and services offered by PharmaTrace for serialization and track and trace are part of the company's portfolio of offerings in the area of digitization for healthcare companies worldwide.

Our Modules



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