

## PROBLEM & PROBLEM UNDERSTANDING

Specify the business problem

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PROJECT NAME	Drugs traceability
REMARKS	I

### Specification of business problem:

**Counterfeit Drugs:** Counterfeit drugs can infiltrate the market, posing serious health risks to patients. Traceability is essential to confirm the authenticity and integrity of pharmaceutical products.

**Regulatory Compliance:** The pharmaceutical industry is subject to strict regulations and compliance requirements. Traceability helps meet these standards, such as the Drug Supply Chain Security Act (DSCSA) in the United States.

**Product Recalls:** In the event of product recalls due to safety concerns or quality issues, traceability is critical for identifying affected batches and minimizing risks.

**Supply Chain Efficiency:** Traceability systems can improve supply chain efficiency by reducing errors, minimizing losses, and optimizing inventory management.

**Adverse Event Monitoring:** Efficient traceability systems allow quick identification of the source and distribution of products involved in adverse events or side effects.

**Product Expiry Management:** Ensuring that expired drugs are not dispensed to patients is vital for patient safety and regulatory compliance.

**Fraud Prevention:** Traceability can deter and detect fraud within the supply chain, such as theft, diversion, or illegal distribution of pharmaceuticals.

**Patient Safety:** Ultimately, the business problem in drug traceability is about safeguarding patient safety by ensuring that they receive genuine, safe, and effective pharmaceutical products.

### **Secure cataloguing:**

**Data Standardization:** Implement a standardized data format for cataloging drug information. This could include details like the drug's name, batch number, manufacturing date, expiration date, and serial number. Adhering to industry standards, such as GS1 standards, can facilitate interoperability.

**Unique Identifiers:** Assign unique identifiers (e.g., serial numbers, barcodes, or QR codes) to each unit or batch of drugs. These identifiers should be difficult to replicate or forge.

**Secure Databases:** Maintain secure, centralized databases that store drug information. These databases should be protected from unauthorized access and tampering. Utilize encryption and access controls to enhance security.

**Blockchain Technology:** Consider implementing blockchain technology for secure cataloguing. Blockchain offers an immutable ledger where each transaction is recorded, providing transparency and security. Any changes are easily detectable.

**Secure Communication:** Ensure that data transmission between different nodes in the supply chain is encrypted and secure. Use secure channels for sharing catalog information among stakeholders.

**Authentication and Verification:** Implement mechanisms for authenticating and verifying the drug catalog data. This can include digital signatures, cryptographic techniques, and verification protocols.

**Real-time Updates:** Enable real-time updates to the catalog as drugs move through the supply chain. This ensures that stakeholders have access to the most current information.

### **Efficient borrowing and returns:**

#### **Returns Process:**

**Verification:** Upon return, verify the returned drugs against the documentation. This includes checking the condition, quantity, and expiration date.

**Electronic Records:** Ensure that the returns are recorded electronically, updating the inventory in real-time.

**Expiration Management:** Implement a system for managing drug expiration dates. Returned drugs that are close to expiration should be checked and possibly disposed of or re-allocated.

**Quarantine:** If there are any doubts about the condition or authenticity of the returned drugs, have a process to quarantine and investigate them.

**Reconciliation:** Regularly reconcile borrowed and returned drug records to identify any discrepancies.

**Notification of Borrowers:** Notify borrowers when their borrowed drugs have been successfully returned and are available for borrowing by others.

**Auditing and Compliance:** Regularly audit the borrowing and returns processes to ensure compliance with regulatory requirements.

Integration: If possible, integrate borrowing and returns systems with the broader drug traceability system to maintain a single source of truth for all drug-related data.

### **Borrowing Process:**

**Request and Authorization:** Ensure a standardized process for healthcare providers, pharmacies, or other stakeholders to request drugs. This should involve proper authorization and validation of the request.

**Inventory Visibility:** Maintain real-time visibility into drug inventory. This allows for efficient allocation of drugs and prevents overborrowing.

**Electronic Ordering:** Implement electronic ordering systems that enable healthcare providers to request drugs electronically. This reduces paperwork and streamlines the process.

**Barcoding or RFID:** Use barcodes or RFID technology to accurately identify borrowed drugs, ensuring they are correctly matched to the request.

**Documentation:** Require proper documentation of the borrowing transaction. This includes details such as the borrower's information, the drugs borrowed, quantities, and expected return date.

**Notification and Alerts:** Implement a system that notifies the lending party when drugs are borrowed. Set up alerts for overdue returns.

