Requirement Analysis

Date	06 November 2023
Team ID	NM2023TMID02201
Project Title	Project- Drug Traceability

Functional Requirement:

Functional requirements for drug traceability in blockchain include:

1. **Data Recording**: The system should enable the recording of detailed drug information, including batch numbers, expiration dates, manufacturing data, and serial numbers, on the blockchain.

2. **Authentication and Verification**: Users should be able to authenticate the origin and verify the authenticity of drugs at any point in the supply chain by accessing blockchain records.

3. **Transaction Tracking**: The blockchain should provide a complete and immutable history of drug transactions, allowing users to trace the journey of a drug from manufacturer to end-user.

4. **Interoperability**: The system should support interoperability with existing supply chain management systems and ensure seamless data sharing among stakeholders.

5. **Smart Contracts**: Implement smart contracts to automate processes such as quality control, compliance checks, and alerts for recalls or expired products.

6. **Privacy and Security**: Ensure that sensitive data is protected and that only authorized parties have access to specific information while maintaining data integrity and security.

7. **Compliance Reporting**: Generate compliance reports based on regulatory requirements, making it easier for regulatory bodies to access necessary data for inspections.

8. **Notification and Alert System**: Implement a notification system that alerts relevant stakeholders in real-time about issues like product recalls or quality control failures.

9. **User Access Control**: Administer role-based access control to ensure that only authorized personnel can make changes to blockchain data.

10. **Scalability**: The system should handle a growing volume of transactions and data as the supply chain expands.

Operational Requirement:

Operational requirements for drug traceability are:

1. Data Standardization: Standardize data formats and structures to ensure consistency across the supply chain. This includes product identifiers, batch/lot numbers, expiration dates, manufacturing information, and more.

2. Data Capture: Implement mechanisms to capture and record data at various points in the supply chain, including manufacturers, distributors, pharmacies, and healthcare providers.

3. Unique Identifiers: Assign unique identifiers to each drug product, such as serial numbers, barcodes, or QR codes, to facilitate tracking and tracing.

4. Data Integrity: Ensure the integrity and security of data by using cryptographic hashing and digital signatures to prevent unauthorized tampering.

5. Interoperability: Enable different stakeholders in the pharmaceutical supply chain to access and contribute to the blockchain, promoting transparency and interoperability.

6. Compliance: Ensure compliance with relevant regulations, such as the Drug Supply Chain Security Act (DSCSA) in the United States or similar regulations in other countries.

7. Smart Contracts: Implement smart contracts to automate various processes, such as verifying the authenticity of products, triggering alerts for recalls, and managing inventory.

8. User Access Control: Define roles and permissions for various users, limiting access to sensitive data to authorized personnel only.

9. Decentralization: Utilize a permissioned blockchain network to maintain control and privacy while still allowing for collaboration among trusted participants.

10. Scalability: Design the blockchain infrastructure to handle a high volume of transactions and data as the pharmaceutical supply chain grows.

11. User-Friendly Interfaces: Develop user interfaces and applications that make it easy for participants to interact with the blockchain, report incidents, and retrieve information.

12. Auditing and Reporting: Incorporate features for auditing and generating reports to comply with regulatory requirements and internal audits.

13. Real-Time Updates: Ensure that data updates and transactions are processed in real-time or near-real-time to enable prompt actions when issues arise.

Techenical Requirements:

Technical requirements for drug traceability in blockchain:

1. Blockchain Platform Selection: Choose a suitable blockchain platform based on factors like scalability, consensus mechanism, privacy features, and compatibility with the pharmaceutical supply chain's needs. Options include public blockchains (like Ethereum), private blockchains (like Hyperledger Fabric), or consortium blockchains.

2. Data Standardization: Establish standardized data formats and schemas for drug-related information, such as product identifiers, batch/lot numbers, expiration dates, manufacturing data, and product provenance.

3. Smart Contracts: Develop and deploy smart contracts to automate processes such as verifying product authenticity, handling recalls, and managing inventory. These contracts should be well-audited and secure.

4. Cryptographic Security: Utilize cryptographic techniques, such as hashing and digital signatures, to ensure data integrity and authentication. Secure key management is critical to safeguard cryptographic keys.

5. Consensus Mechanism: Determine an appropriate consensus mechanism (e.g., Proof of Work, Proof of Stake, or Practical Byzantine Fault Tolerance) that aligns with the security and performance requirements of the system.

6. Identity Management: Implement a robust identity management system to verify and authenticate participants on the network. This may involve public-key infrastructure (PKI) or other identity verification methods.

7. Permissioned Network: Create a permissioned blockchain network where only authorized participants can join and contribute to the system. This helps maintain control and privacy.

8. Data Privacy: Implement privacy features to protect sensitive data and ensure that only authorized parties can access specific information. Techniques like zero-knowledge proofs can be used to protect confidentiality.

9. Data Storage: Choose a suitable storage solution for storing off-chain data, such as product information and documents, while storing essential data on-chain for traceability.

10. Scalability: Design the blockchain infrastructure to handle a high volume of transactions and data as the pharmaceutical supply chain grows. Consider solutions like sharding, sidechains, or state channels.

11. Interoperability: Ensure that the blockchain system can interoperate with existing systems used by stakeholders in the pharmaceutical supply chain, such as ERP systems or supply chain management software.
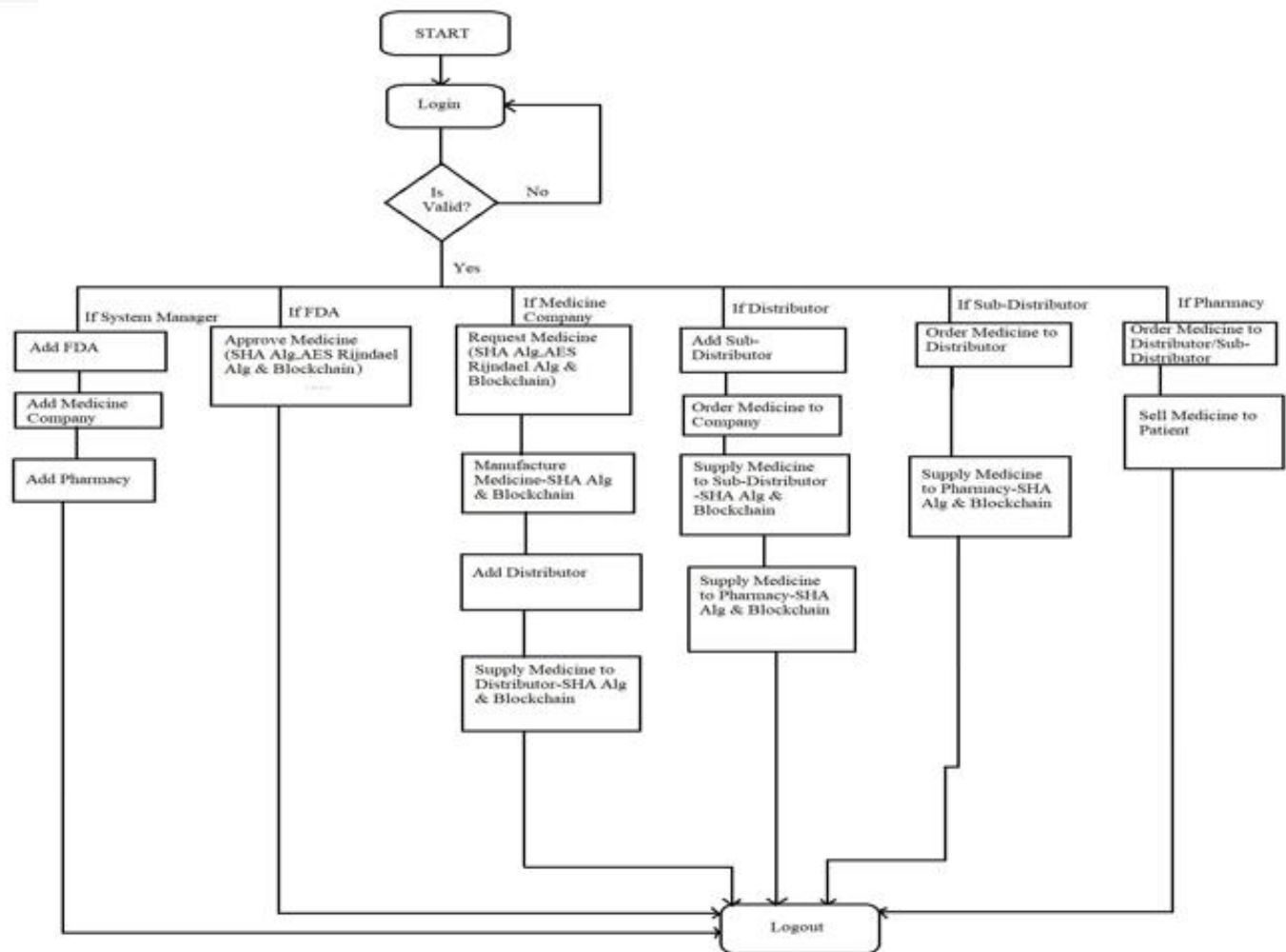
Flow Chart:

Figure 5: Design Flow