

Business Requirements

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Team ID	NM2023TMID02201
Project Name	Project – Drug Traceability
Maximum Marks	Marks

Business Requirements:

1. Regulatory Compliance

Ensure compliance with local and international regulations, such as the Drug Supply Chain Security Act (DSCSA) in the United States or the Falsified Medicines Directive (FMD) in Europe.

2. Data Integrity:

Maintain the integrity of drug data throughout the supply chain, preventing unauthorized access or tampering with sensitive information.

3. Supply Chain Transparency

Enable real-time visibility into the movement and status of pharmaceutical products across the supply chain, from manufacturers to patients.

4. Serialization:

Implement a unique identification system (serialization) for each drug unit, allowing for tracking and tracing at the individual product level.

5. Data Standardization:

Use standardized data formats and terminology to ensure interoperability and data consistency among various stakeholders in the supply chain.

6. Interoperability

Ensure that the blockchain system can integrate with existing supply chain management systems, including Enterprise Resource Planning (ERP) and Warehouse Management Systems (WMS).

7. Identity and Access Management:

Establish secure user access controls and authentication mechanisms to limit access to authorized personnel and entities

8. Privacy and Confidentiality:

Protect sensitive data and patient information, ensuring that only authorized individuals or organizations have access to specific data elements.

9. Smart Contracts:

Utilize smart contracts to automate and enforce business rules, such as verifying the authenticity of products, triggering alerts for recalls, and facilitating payments.

10. Event Logging:

Maintain a detailed event log of all transactions and changes to the blockchain, allowing for auditing and accountability

11. Scalability:

Design the blockchain system to handle a high volume of transactions, especially in large pharmaceutical supply chains

12. User-Friendly Interfaces

Develop user interfaces that are easy to use for different stakeholders, including manufacturers, distributors, pharmacists, and regulatory authorities.