DRUG TRACEABILITY

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CHAPTER-1

INTRODUCTION

1.1 PROJECT OVERVIEW

A drug traceability is a comprehensive initiative that focuses on the meticulous monitoring of pharmaceutical products throughout their lifecycle within the supply chain. It involves assigning unique serial numbers or codes to individual drug packages, enabling their identification and tracking. Data related to drug manufacturing, packaging, and distribution is recorded in a centralized database. Verification processes are implemented to ensure the authenticity of drugs at various points in the supply chain, thereby reducing the risk of counterfeit or substandard products.

Compliance with stringent regulatory requirements, such as the Drug Supply Chain Security Act (DSCSA) in the United States and the Falsified Medicines Directive (FMD) is a primary goal. The integration of technologies like barcoding, RFID, and block chain plays a crucial role in this endeavor. Overall, the project aims to enhance patient safety, improve transparency, and safeguard public health by maintaining the integrity of the pharmaceutical supply chain through meticulous tracking, reporting, and auditing.

1.2 PURRPOSE

Drug traceability's overarching purpose is to enhance patient safety and the integrity of the pharmaceutical supply chain. Ensures patient safety by preventing counterfeit and substandard drugs from reaching consumers Enables rapid recall and removal of unsafe or faulty products from the market. Promotes compliance with regulatory requirements in the pharmaceutical industry. Improves supply chain efficiency by tracking the movement of drugs at every stage. Facilitates transparency and accountability among stakeholders, the global issue of counterfeit drugs, safeguarding public health.

CHAPTER -2

LITERATURE SURVEY

2.1 EXISTING PROBLEM

Roughly one-third of the world's countries lack effective drug regulatory agencies, making them easy prey for counterfeiters. The absence of anti-counterfeiting measures exposes millions of people to potentially lethal chemicals and undermines the growth strategies of companies looking for new markets. Serialization is the process of assigning unique numbers to each product pack. Through serialization, manufacturers can identify every unit that leaves their facility, no matter where the product ends up along the supply chain.

2.2 REFERENCES

FDA Drug Supply Chain Security Act (DSCSA): The DSCSA is a federal law that outlines requirements for drug traceability. You can find information and guidance on the FDA's website.
EU Falsified Medicines Directive (FMD): The FMD is a European Union regulation that focuses on preventing falsified medicines from entering the legal supply chain. Information about the FMD can be found on the European Medicines Agency (EMA) website.
World Health Organization (WHO) Guidelines: WHO provides guidelines and resources related to pharmaceutical traceability and serialization. Their website is a valuable resource for international standards.

2.3 PROBLEM STATEMENT DEFINITION

"Ensuring the traceability of pharmaceutical products is essential to guarantee their authenticity and safety. The problem we aim to address is the lack of a comprehensive and standardized system for tracking drugs from manufacturing to distribution. This deficiency leads to challenges such as counterfeiting, quality control issues, and inefficient recall processes. Our goal is to establish a robust and universally adopted drug traceability framework that enhances transparency, reduces the risk of counterfeit drugs, and facilitates swift responses to safety concerns." This problem statement sets the stage for developing solutions to improve drug traceability in the pharmaceutical industry.

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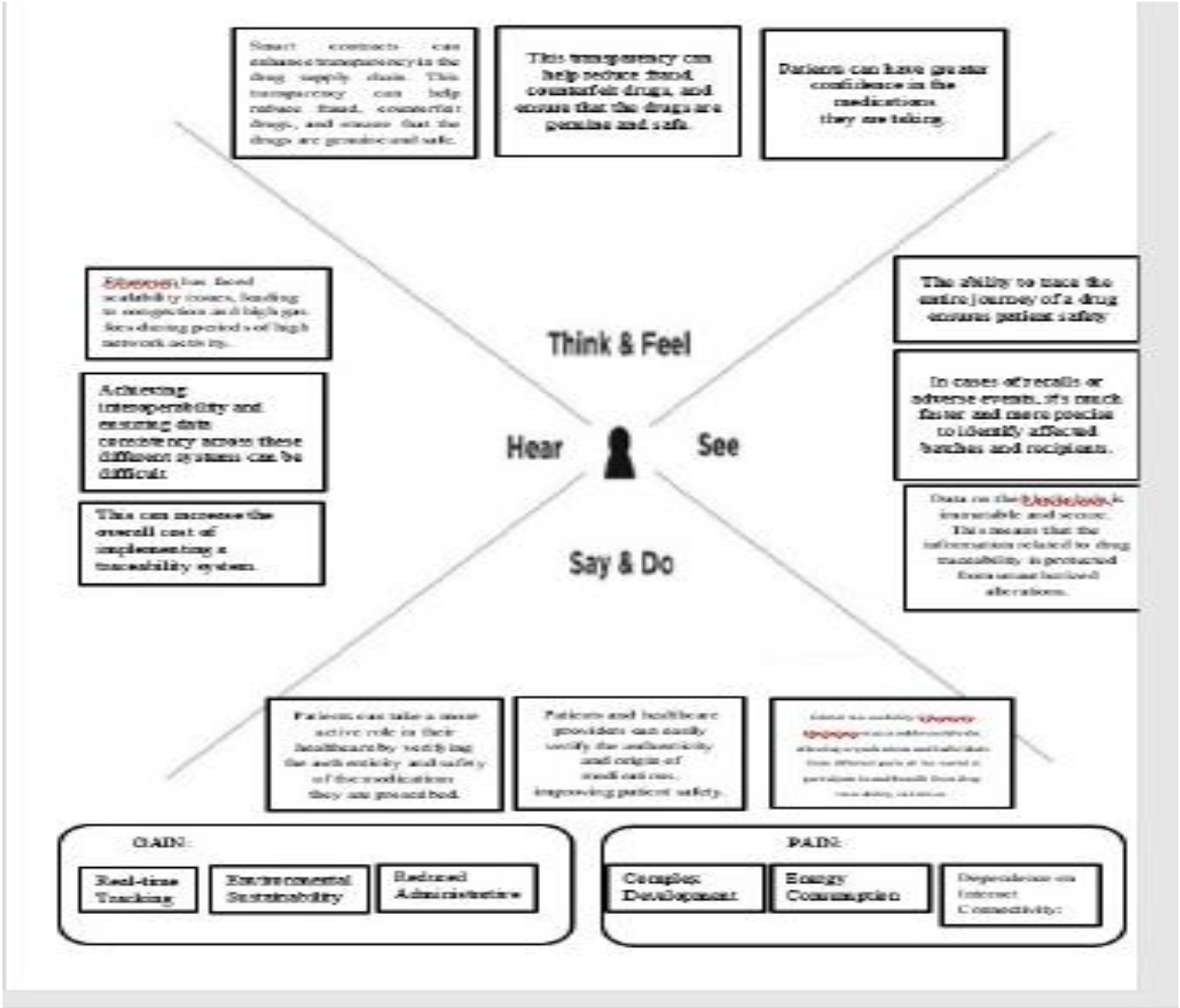
IDEATION & PROPOSED SOLUTION

3.1 EMPATHY MAP CANVAS



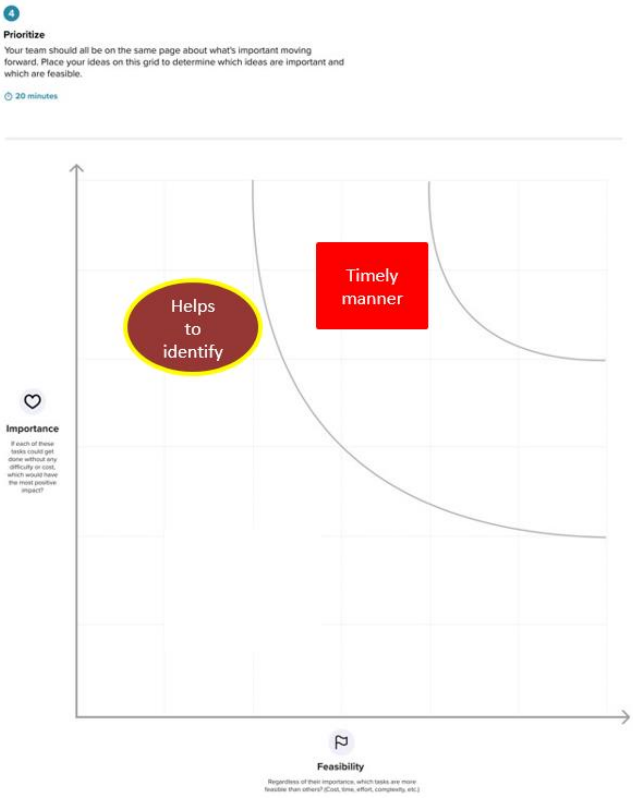
3.2 IDEATION AND BRIANSTORMING

Problem statement

Estimated that about 30 percent of the world's population lack regular access to essential medicines and that in the poorest parts of Africa and Asia, the percentage is more than 50 percent [2-4]. Developing countries have limited provisions to treatments for infectious diseases, which are the main cause of morbidity and mortality in developing countries, and the supply of medicine to cure other diseases, is difficult or depended on supplies of develop countries as charity or WHO grants. Infectious and parasitic diseases account for only five percent of the disease burden in high-income countries [6] but represent about 50 percent of the developing countries' burden of disease . Essential medicines are diverted to these countries by drug traffickers and criminals. Mostly essential drugs are available illicitly in black markets on very high price, contaminated or inferior quality. These drugs do not improve patient health and many occasion poised serious health condition. Studies have shown that, out of 1,556 new active substances developed between 1975 and 2004, only 21 were intended for treating neglected tropical diseases including tuberculosis and malaria . Criminals and drug traffickers are taking advantage of existing inaccessibility of medicine for public and supply counterfeit drugs into market.

Step-2: Brainstorm, Idea Listing and Grouping

STEP 3:IDEATION PRIORITAZATION



CHAPTER –4
REQUIREMENT ANALYSIS

4.1 FUNCTIONAL REQUIREMENT

Data Capture and Storage:
The system should be able to capture and store data related to each drug, including information about its production, distribution, and dispensing.

Real-time Tracking:
The ability to track the location and status of drugs in real-time, especially during transportation and distribution.

User Authentication:
Only authorized personnel should be able to access and modify the traceability.

Alerts and Notifications:
Generate alerts or notifications for any suspicious or unauthorized activities, ensuring the security and integrity of the drug supply chain.

Compliance with Regulations:
Ensure that the system complies with relevant regulations and standards, such as the Drug Supply Chain Security Act (DSCSA) in the United States.

Integration with Serialization Technologies:
Implement serialization technologies (e.g., barcodes, QR codes, RFID) to facilitate traceability. These functional requirements are crucial for drug traceability to enhance patient safety, combat counterfeit drugs, and meet regulatory requirements.

4.2 NON FUNCTIONAL REQUIREMENT

Security:

Ensuring the security of data and transactions is paramount. Requirements should include data encryption, access control, authentication, and audit trails to prevent unauthorized access and tampering.

Scalability:

The system should be able to handle an increasing volume of drug transactions and data as the industry grows. Scalability requirements may include load balancing, distributed architecture, and performance optimization.

Performance:

The system must be responsive and efficient. Performance requirements may specify response times for various operations and should consider peak loads.

Reliability:

Drug traceability is critical to patient safety. Therefore, the system must be highly reliable, with requirements for uptime, fault tolerance, and disaster recovery.

Compliance:

The system should comply with industry-specific regulations and standards, such as the Drug Supply Chain Security Act (DSCSA) or Falsified Medicines Directive (FMD)

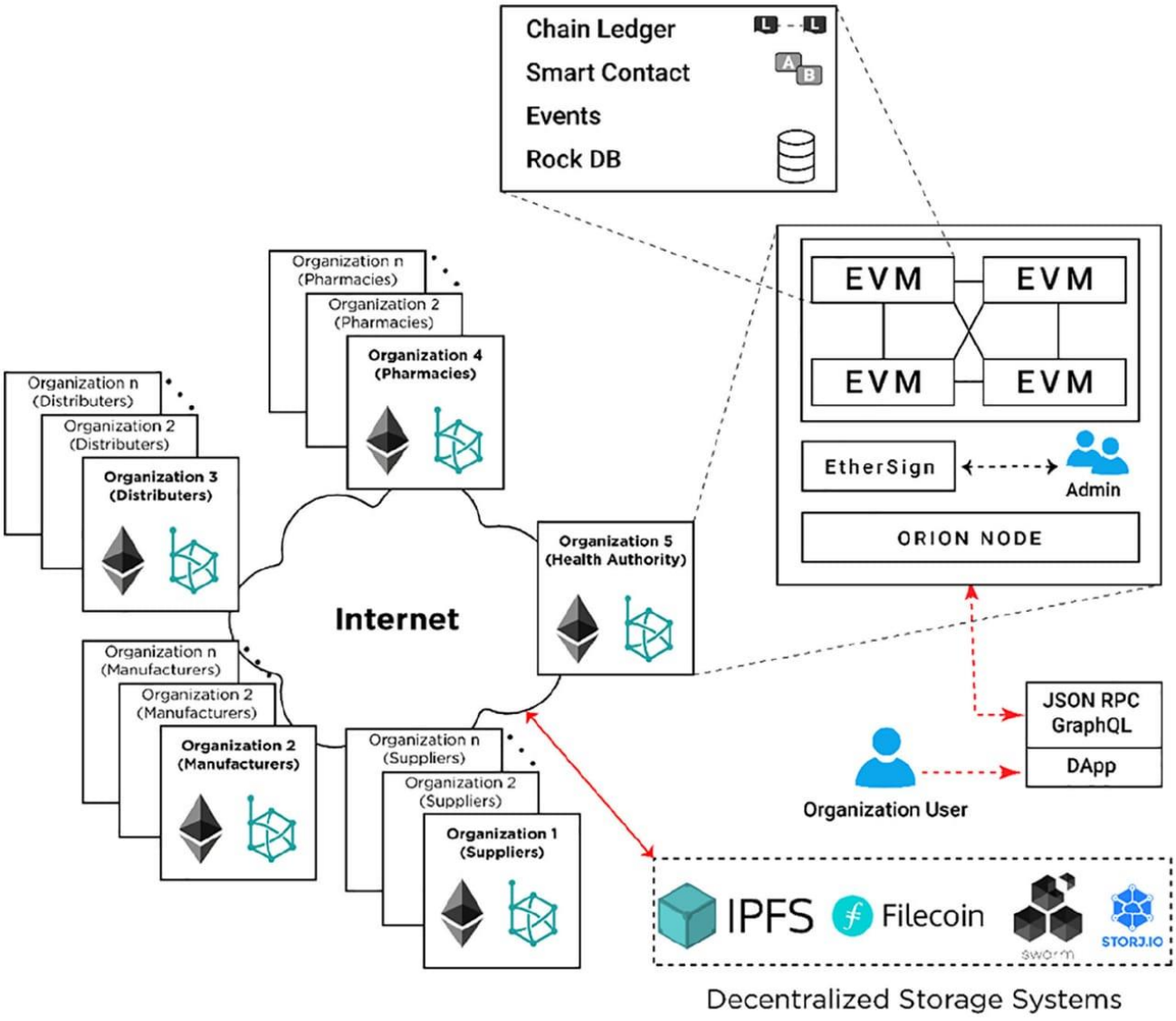
Interoperability:

To support a seamless flow of information across the pharmaceutical supply chain, the system should be able to interoperate with various stakeholders' systems. This requires standards adherence and compatibility.

CHAPTER-5

PROJECT DESIGN

5.1 DATA FLOW DIAGRAMS & USER STORIES



USER STORIES

User types	Functional requirement (Epic)	User story number	User story/task	Acceptance criteria	priority	Team member
Person(social User)	Level of trace	USN-1	As a pharmaceutical distributor, I want a robust drug traceability system.	The system should support the capture and recording of critical information.	High	MAHA SHREE
		USN-2	I want to verify the authenticity and origin of a drug product.	The system should allow the recording of detailed information .	High	SNEGHA
		USN-3	I want to use a drug traceability system to conduct inspections and audits on pharmaceutical manufacturers.	Users should be able to access and search the database for specific product information .	High	PAVITHRA
		USN-4	I want to use a drug traceability system to quickly access detailed information about the medications .	This user story outlines the need for a drug traceability system .	High	SOWMIYA

5.2 SOLUTION ARCHITECTURE

Solution architecture is a complex process – with many sub-processes – that bridges the gapbetween business problems and technology solutions. Its goals are to:

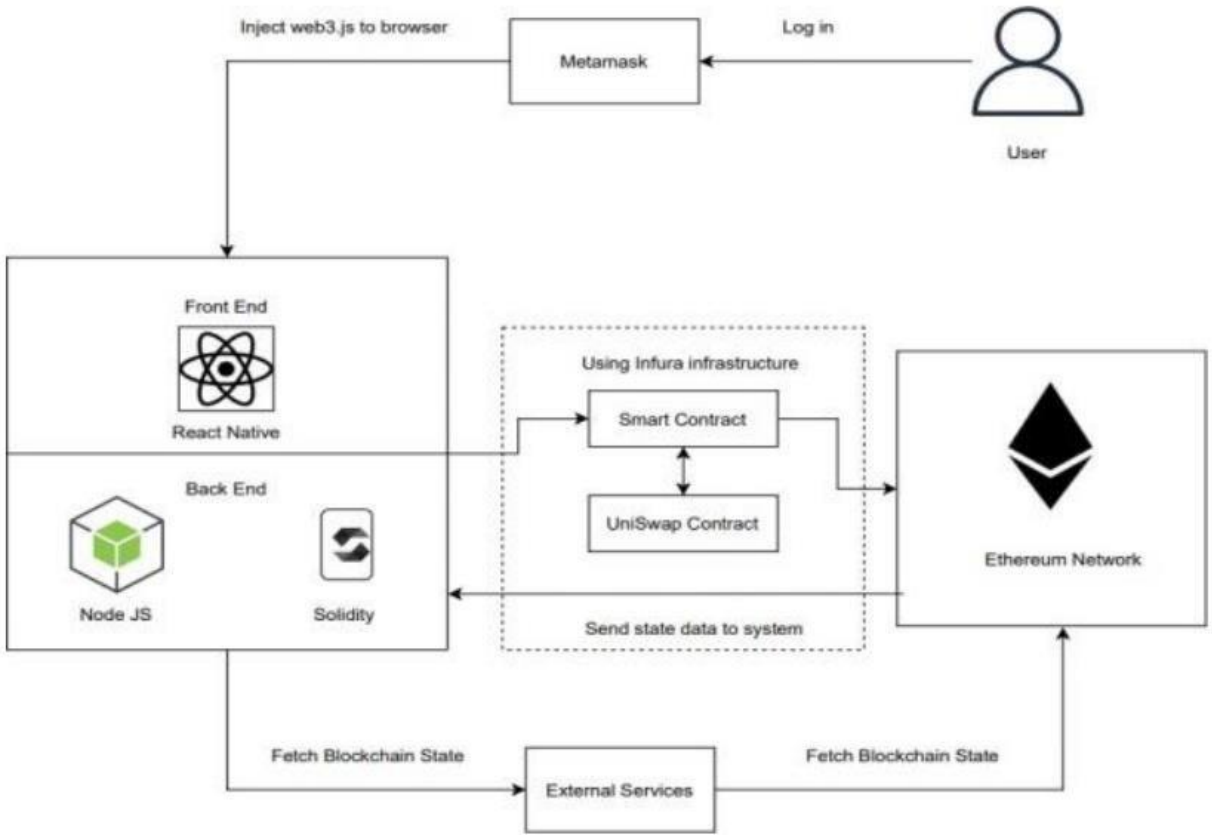
Drug traceability using blockchain involves combining bloc chain technology withvarious other components to create a secure and transparent system for tracking the supply chain of pharmaceuticals.

Choose a suitable block chain platform, such as Ethereum, or a private blockchain,depending on your specific requirements.

Set up nodes and establish a network that includes all the relevant participants in thedrug supply chain, including manufacturers, distributors, pharmacies, and regulatory authorities.

Store information about each drug, including its manufacturing details, batch numbers, expiration dates, and unique serial numbers on the blockchain.

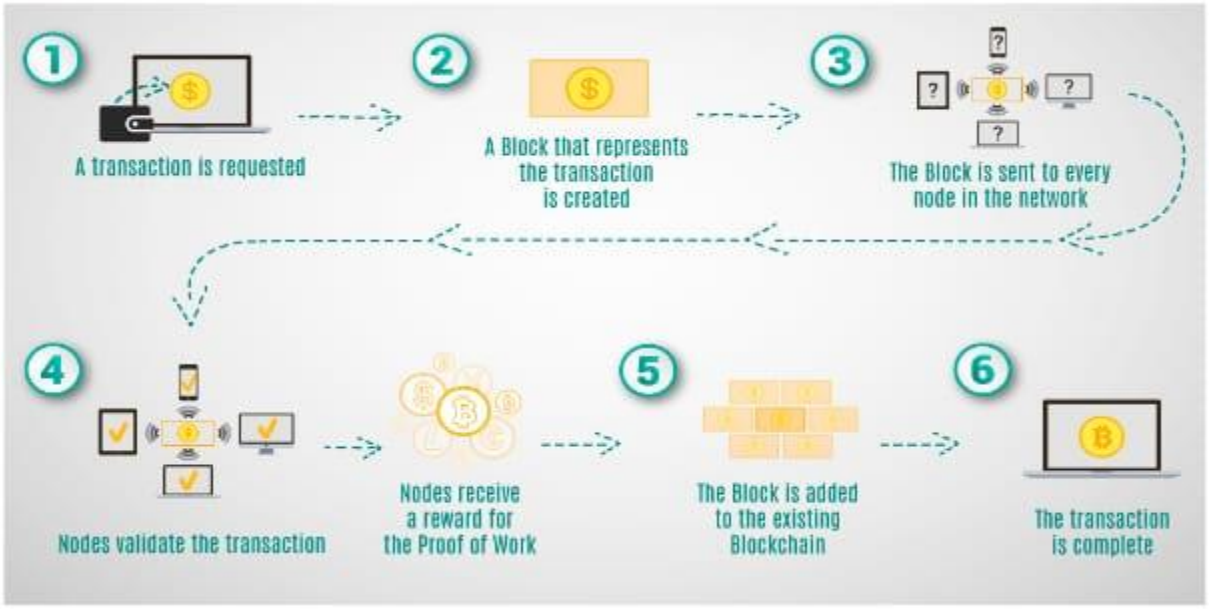
Solution Architecture Diagram



CHAPTER 6

PROJECT PLANNING AND SCHEDULING

6.1 TECHNICAL ARCHITECTURE



6.2 SPRINT PLANNING AND ESTIMATION

Task Breakdown:
Break each user story into specific tasks, like "Set up barcode scanner hardware," "Develop barcode scanning feature," and "Test barcode scanning."
Estimation:
Use story points or time-based estimates for each task. For instance, "Setting up hardware" might be 2 story points, "Developing the feature" could be 5 points, and "Testing" might be 3 points.
Prioritization:
Rank the user stories and tasks based on their importance and dependencies.
Sprint Commitment:
Select a set of user stories and tasks that fit within the sprint's capacity, considering the team's velocity (past performance).
Daily Standups:
Hold daily standup meetings to track progress and make any necessary adjustments during the sprint.

6.3 SPRINT DELIVERY SCHEDULE:

Sprint delivery schedules for drug traceability can vary based on the specific project requirements, team capacity, and development complexity. It typically involves breaking down the work into smaller tasks or user stories and estimating their completion time. Common sprint lengths are 2 weeks, 3 weeks, or 4 weeks.

Sprint Planning: Define the sprint goals and select user stories or features to work on.

Daily Stand-ups: Short daily meetings to discuss progress and address any obstacles.

Development: Develop and test the software features, ensuring traceability of drugs.

Sprint Review: Showcase the completed work to stakeholders and gather feedback.

Sprint Retrospective: Reflect on the sprint, identify improvements, and plan the next one**.**

CHAPTER-7

CODING AND SOLUTION

7.1 FEATURE

Unique Product Identifier (UPI):

A distinct code for each drug product, such as a serial number, barcode, QR code, or RFID tag.

Batch or Lot Number:

A specific code or number that identifies a group of products manufactured together.

Manufacturer Information:

Details about the pharmaceutical company, including name, location, and contact information.

Expiration Date:

The date until which the drug is guaranteed to be effective and safe.

Manufacturing Date:

The date on which the drug was produced.

Drug Name and Description:

Information about the drug's name, dosage, and usage instructions.

Regulatory Compliance Information:

Codes or indicators to confirm that the product complies with relevant regulations and standards.

Secure Authentication:

Security features to prevent counterfeiting, such as tamper-evident packaging, holograms, or digital signatures.

Supply Chain Information:

Information about the drug's journey through the supply chain, including distribution points and handling.

Digital Records:

Integration with a central database or blockchain for recording and accessing information about each product's history.

Track and Trace:

Capability for scanning or querying the code to track the drug's movement from manufacturing to the end-user.

Anti-Counterfeiting Measures:

Security features that are difficult to replicate, like unique holograms, invisible ink, or other covert markers.

Integration with Mobile Apps or Online Platforms:

Users can scan the code with a mobile app or enter it online to access detailed information about the drug.

CHAPTER- 8

PERFORMANCE TESTING

8.1 PERFORMANCE METRICS

Accuracy: Measure the percentage of correctly identified and traced drug products throughout the supply chain.

Traceability Rate: Calculate the percentage of drugs successfully traced from manufacturer to end-user or patient.

Timeliness: Assess the speed at which drug traceability data is updated and made available, ensuring real-time or near-real-time tracking.

Data Completeness: Measure the percentage of required data fields that are correctly filled in the traceability system.

Data Integrity: Evaluate the quality and reliability of traceability data, ensuring it hasn't been tampered with or altered.

Error Rate: Calculate the percentage of traceability data that contains errors, discrepancies, or inconsistencies.

Compliance Rate: Assess adherence to relevant regulations and standards, such as the Drug Supply Chain Security Act (DSCSA) in the United States.

Security: Measure the effectiveness of security measures in protecting traceability data from unauthorized access or cyber threats.

Auditability: Assess the ability to audit and review the entire drug traceability process, including historical data.

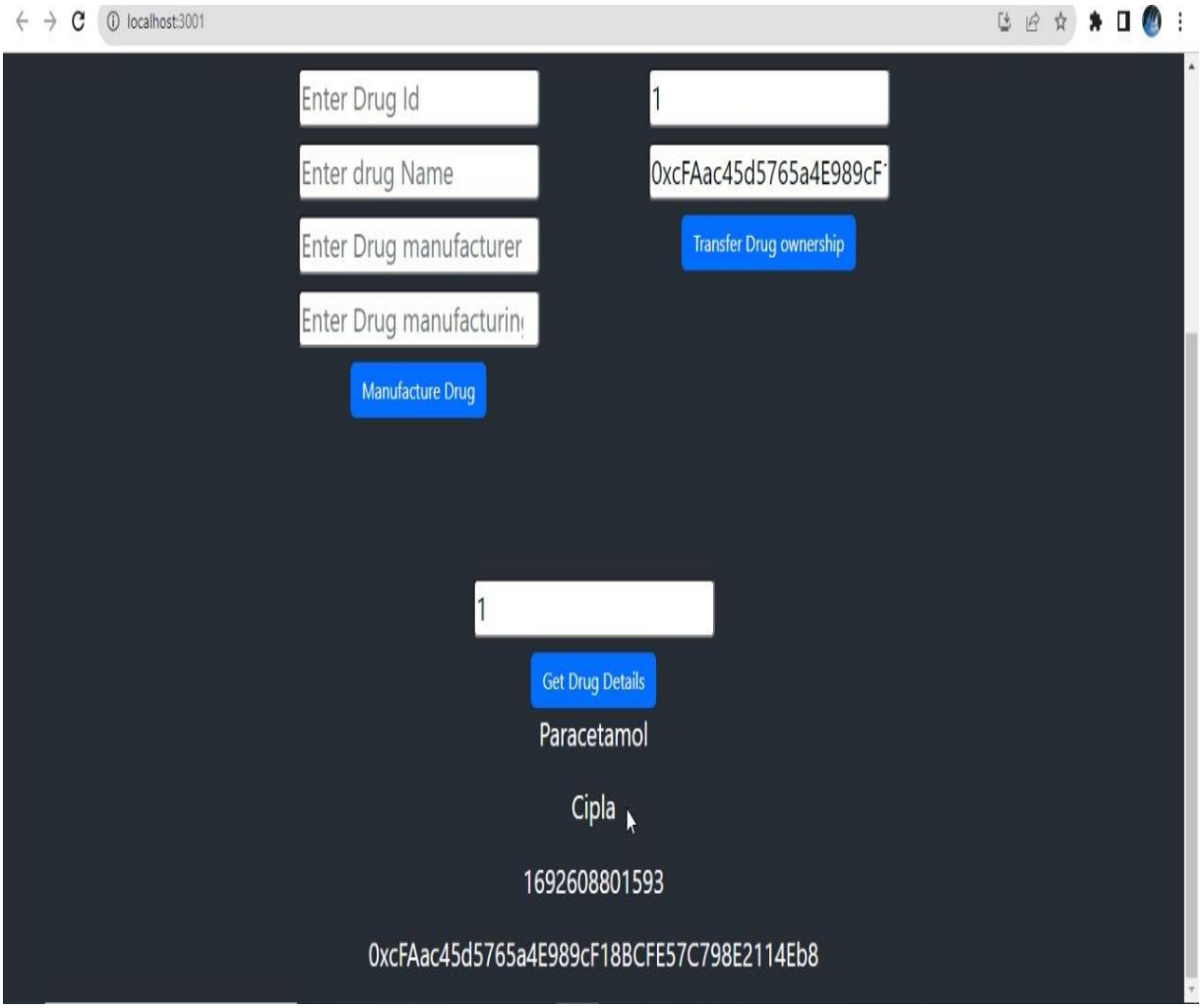
Scalability: Determine if the traceability system can handle increasing volumes of drug products as the business grows.

Cost Efficiency: Evaluate the cost-effectiveness of implementing and maintaining the traceability system.

CHAPTER -9

RESULTS

9.1 OUTPUT SCREENSHOT



CHAPTER -10

ADVANTAGES:

* Patient safety
* Quality control
* Regulatory compliance
* Supply chain efficiency
* Recall management
* Counterfeit detection
* Data analytics
* Transparency
* Accountability
* Public health protection

DISADVANTAGES:

* Implementation costs can be high.
* Data privacy concerns may arise.
* Technical complexity and interoperability issues.
* Potential resistance to adoption.
* Supply chain delays could occur.
* Regulatory burdens and increased complexity.

CHAPTER-11

CONCLUSION

drug traceability is a fundamental component of pharmaceutical supply chain management, with far-reaching implications for patient safety, regulatory compliance, and the integrity of the industry as a whole. The ability to track the movement of drugs from the manufacturer to the end-user or patient provides a robust foundation for ensuring the authenticity, quality, and safety of pharmaceutical products.Effective drug traceability systems rely on accurate, timely, and secure data, with key performance metrics that encompass accuracy, traceability rate, data completeness, and compliance with regulations. These systems not only enable rapid recalls in case of safety concerns but also help reduce counterfeiting and promote overall transparency within the supply chain. As the pharmaceutical industry continues to evolve, the importance of drug traceability becomes even more pronounced. The ability to adapt, scale, and interoperate with other stakeholders in the supply chain is essential for success. By prioritizing drug traceability and adhering to best practices, the industry can maintain patient trust, meet regulatory requirements, and ultimately ensure the safety and efficacy of pharmaceutical products.

CHAPTER -12

FUTURE SCOPE

Blockchain Technology: Blockchain's decentralized and immutable ledger has the potential to revolutionize drug traceability by enhancing data security and transparency. Blockchain can be used to create tamper-proof records of drug transactions and movements throughout the supply chain.

Internet of Things (IoT): IoT devices and sensors can provide real-time data on the location and condition of pharmaceutical products. This can enhance traceability and enable proactive monitoring of temperature, humidity, and other factors that can affect drug quality.

Artificial Intelligence (AI) and Machine Learning: AI can be used to analyze vast datasets and identify patterns that help in detecting anomalies, counterfeit drugs, or supply chain inefficiencies. Machine learning algorithms can improve the accuracy of drug traceability systems.

Serialization and Unique Identifiers: Many countries have introduced serialization requirements that mandate unique identifiers for drug products. The future will likely see increased adoption of such measures to enhance traceability and combat counterfeiting.

Global Harmonization: Efforts to harmonize drug traceability standards and regulations at the international level will likely continue. This can simplify compliance for pharmaceutical companies operating in multiple markets.

Enhanced Security: The future of drug traceability will focus on improving the security of data and ensuring protection against cyber threats. Data encryption, authentication, and access control will be paramount.

Data Sharing and Interoperability: Interoperable systems that facilitate seamless data sharing among supply chain stakeholders will become increasingly important. Collaboration between manufacturers, distributors, regulators, and healthcare providers will be critical.

CHAPTER-13

SOURCE CODE

```
// SPDX-License-Identifier: MIT
pragma solidity ^0.8.0;

contract DrugTracking {
    address public owner;

    struct Drug {
        string name;
        string batchNumber;
        uint256 manufacturingDate;
        uint256 expirationDate;
        address manufacturer;
        address currentOwner;
    }

    mapping(bytes32 => Drug) public drugs;
    bytes32[] public drugKeys;

    event DrugCreated(bytes32 indexed key, string name, string batchNumber,
address manufacturer);
    event DrugTransferred(bytes32 indexed key, address from, address to);

    modifier onlyOwner() {
        require(msg.sender == owner, "Only the owner can perform this action");
        _;
    }

    constructor() {
        owner = msg.sender;
    }

    function createDrug(
        string memory _name,
        string memory _batchNumber,
        uint256 _manufacturingDate,
       uint256 _expirationDate
```

```
    ) public onlyOwner {
        bytes32 key = keccak256(abi.encodePacked(_name, _batchNumber,
msg.sender, now));
        drugs[key] = Drug(_name, _batchNumber, _manufacturingDate,
_expirationDate, msg.sender, msg.sender);
        drugKeys.push(key);
        emit DrugCreated(key, _name, _batchNumber, msg.sender);
    }

    function transferDrug(bytes32 _key, address _newOwner) public {
        Drug storage drug = drugs[_key];
        require(msg.sender == drug.currentOwner, "Only the current owner can
transfer the drug");
        require(block.timestamp < drug.expirationDate, "This drug has expired");
        drug.currentOwner = _newOwner;
        emit DrugTransferred(_key, msg.sender, _newOwner);
    }

    function getDrugDetails(bytes32 _key) public view returns (
        string memory name,
        string memory batchNumber,
        uint256 manufacturingDate,
        uint256 expirationDate,
        address manufacturer,
        address currentOwner
    ) {
        Drug storage drug = drugs[_key];
        return (
            drug.name,
            drug.batchNumber,
            drug.manufacturingDate,
            drug.expirationDate,
            drug.manufacturer,
            drug.currentOwner
        );
    }



function getAllDrugKeys() public view returns (bytes32[] memory) {
```

```
 return drugKeys
    }
}
```

DEMO LINK:

https://youtu.be/4VnEBT2pKq0?si=IcRSJjlu6uV0WiI3

GITHUB LINK:

https://github.com/sneghaG/Drug-Traceability.git