System Requirements Specification

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Contents

1 Introduction

1.1 System Purpose

The intended software system seeks to enhance the logistical processes involved in distributing the COVID-19 vaccine for Pharma company XYZ. Its main objective is to facilitate the efficient and secure global distribution of the vaccine from the organization's two manufacturing plants in the US and one in the EU. Key stakeholders in this initiative include Pharma company XYZ, user agencies, supplier organizations, support agencies, and certifiers or certifying bodies. The primary function of the system is to coordinate the entire logistics chain for the distribution of the COVID-19 vaccine. This encompasses activities from manufacturing to shipment and delivery, placing a strong emphasis on preserving the vaccine's quality and integrity throughout the entire process. The system's goal is to ensure the timely and precise delivery of the vaccine to its designated destinations, while adhering to cold chain requirements to uphold its efficacy.

1.2 System Scope

The system or subsystem to which this OpsCon applies is the software architecture for the global distribution of Pharma company XYZ's COVID-19 vaccine.

The system's primary goal is to ensure the efficient and secure global distribution of the vaccine, spanning from the organization's manufacturing plants in the US and EU. Key stakeholders, including Pharma company XYZ, user groups, and supplier organizations, have been identified.

1. **Users:**
    - *Representation:* Involves stakeholders such as healthcare professionals, government agencies, and logistics personnel.
    - *Purpose:* Users refer to this document to ensure that their specific needs and requirements are accurately represented by their designated representatives. It offers them an opportunity to validate whether the supplier's understanding aligns with their expectations.
2. **Acquirers:**
    - *Representation:* Typically, governmental or regulatory bodies, including entities like the Food and Drug Administration (FDA).
    - *Purpose:* Acquirers use this document to gain a comprehensive understanding of the system requirements, facilitating transparent communication between all parties. This ensures compliance with public health and regulatory standards.
3. **Suppliers:**
    - *Representation:* Refers to organizations responsible for developing and implementing the software architecture for vaccine distribution. Additionally, includes those that create the vaccines and transports them.
    - *Purpose:* It guides organizations responsible for developing and implementing the software architecture, offering a roadmap aligned with defined requirements. Additionally, the document ensures seamless integration with vaccine creation and transportation, specifying functionalities related to these processes. It establishes compliance with regulatory standards, outlining requirements that suppliers must adhere to during development and implementation.

To address these needs, the system is designed to orchestrate the entire logistics chain for distributing the COVID-19 vaccine. It encompasses activities from manufacturing to shipment and delivery, with a strong emphasis on preserving the vaccine's quality and integrity. The primary focus is on ensuring the timely and accurate delivery of the vaccine to its intended destinations, adhering to cold chain requirements to maintain efficacy.

However, it's essential to note that while the system aims to fulfill these objectives, it has defined boundaries. It will not extend beyond its scope of orchestrating logistics and ensuring quality during distribution. The system does not encompass functions unrelated to the vaccine's logistics, serving as a clear delineation of its capabilities.

1.3 System Overview

1.3.1 System Context

The Vaccine Distribution and Management System (VDMS) encompasses several major elements that interact to ensure efficient and secure distribution of Pharma company XYZ's COVID-19 vaccine.
The key elements are:

- **Vaccine Management (VM) Module:** Initiates vaccine shipments, conducts integrity checks, and interfaces with other modules.
- **Logistics and Shipment (LS) Module:** Coordinates vaccine shipments, ensures cold chain compliance, and communicates with VM and FA.
- **Financial and Accounting (FA) Module:** Integrates financial processes with vaccine distribution, supports financial bookkeeping, and ensures accurate financial postings.
- **Analytics and Decision Support (AD) Module:** Leverages real-time temperature data for predictive analytics, reporting, and decision-making.

Additionally, the system includes human elements such as sales personnel, manufacturing plant staff, logistics and shipping teams, accounting and financial personnel, healthcare providers, eligible patients, and executive managers and policymakers. These stakeholders play specific roles in the system's operations.

The interfaces between these modules and stakeholders are carefully defined to ensure seamless communication and collaboration. For example, VM interfaces with LS for shipment initiation, FA for financial integration, and AD for real-time temperature data sharing.

1.3.2 System Functions

Major System Capabilities:

1. Automated Market Sales Order (MSO) creation within 5 minutes of receiving a vaccine order.
2. Inventory allocation and batch allocation based on geographic locations.
3. Real-time temperature monitoring during vaccine transportation.
4. Predictive analytics for strategic vaccine manufacturing.
5. Emergency mode for adaptive vaccine distribution in crises.
6. Maintenance mode for system upkeep and data integrity checks.

Conditions and Constraints:

1. Compliance with cold chain logistics regulations.
2. Timely and accurate financial transactions.
3. Secure vaccine distribution with real-time monitoring.
4. Adherence to regulatory standards, including FDA regulations.
5. System adaptability to different operational modes.

1.3.3 User Characteristics

Sales Personnel:

- Responsible for initiating vaccine orders and MSO creation.
- Number of: Varies
- Device: Desktop or mobile devices

Manufacturing Plant Staff:

- Manages batch allocation and inventory movements.
- Number of: Varies
- Device: Desktop or tablet devices

Logistics and Shipping Teams:

- Coordinates vaccine shipments and ensures cold chain compliance.
- Number of: Varies
- Device: Desktop or mobile devices

Accounting and Financial Personnel:

- Oversees financial processes
- Number of: Varies
- Device: Desktop or tablet devices

Healthcare Provider:

- Administers vaccines to eligible patients
- Number of: Varies
- Device: Desktop or tablet devices

Eligible Patients:

- End-users of the vaccine, integral to the system
- Number of: Varies
- Device: N/A (may receive communication but not directly interact with the system)

Policymakers:

- May not directly interact with the system but significantly influence its operations and decision-making
- Number of: Varies
- Device: Desktop or tablet devices

It is important to note that the nature of the above user uses involves interacting with the system through the defined user interfaces to perform their specific roles, ensuring the smooth operation of the VDMS. Training may be required to adapt to new functionalities, and access controls are implemented to ensure data security.

1.4 Definitions

N/A

2 References

2.1 FDA Regulation 21 CFR 205.50:

Title: Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

Revision: Last amended 10/23/2023

Date: Up to date as of 10/26/2023

Source: https://www.ecfr.gov/current/title-21/section-205.50

2.2 European Commission Guidelines:

Title: Principles of Good Distribution Practice of Active Substances for Medicinal Products for Human Use

Date: Up to date as of 03/19/2015

Source: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015XC0321(01)

2.3 TLS 1.3

Title: TLS 1.3 in Practice: How TLS 1.3 Contributes to the Internet

Date: 06/03/2021

Source: https://dl.acm.org/doi/abs/10.1145/3442381.3450057

3 System Requirements

3.1 Functional Requirements

1. Upon receiving a vaccine order input, the vaccine management module (VM) shall create a Market Sales Order (MSO).
2. The Analytics & decision support module (AD) shall flag the Market Sales Order (MSO) to the executive management to seek business approval.
3. The vaccine management module shall allocate vaccine orders for the North American market to its manufacturing plant in the U.S.
4. The vaccine management module shall allocate vaccine orders for the European market to its manufacturing plant in Europe.
5. The logistics & shipment module (LS) shall generate Stock Transport Orders to move inventory between plants.
6. The Analytics & decision support module (AD) shall execute stock movement notifications between plants.
7. The Analytics & decision support module (AD) shall execute stock procurement alerts.
8. Upon input, the Financial & Accounting (FA) module shall create invoices for the Market Sales Order (MSO).
9. The Analytics & decision support module (AD) shall raise a critical alert if the vaccine shipment faces a temperature excursion during transportation.

10. Dispatched vaccine shipments shall be tracked by the shipment tracking interface using GPS sensors integrated into the shipment for real-time positioning.
11. When a temperature excursion occurs, the logistics & shipment module (LS) shall create an alternate route plan for shipment delivery.
12. The financial postings interface shall offer automated suggestions for financial posting optimization based on historical data AND transaction patterns.
13. Automated posting processes in the financial postings interface shall be triggered by predefined rulesets to reduce manual efforts.
14. Predictive analytics interface shall integrate weather forecasts and traffic conditions to optimize delivery routes dynamically.
15. Predictive analytics interface shall integrate traffic conditions to optimize delivery routes dynamically.
16. The reporting & dashboard interface shall create detailed reports regarding shipping deviations for analysis.
17. The financial postings interface shall display pending customer invoices.
18. The predictive analytics interface shall forecast future cash flows based on pending customer invoices.
19. The batch allocation interface shall prioritize batch allocation based on expiry dates to optimize the utilization of vaccines nearing expiration.
20. The reporting & dashboard interface shall create quarterly audit reports for cold chain logistics partners based on factors such as deliveries completed, shipment spoilage.
21. The inventory management interface shall create automatic submission of reorder requests to manufacturing plants when vaccine batches expire.
22. The shipment tracking interface shall provide tracking of vaccine data such as batch number AND manufacturing plant.

3.2 Usability Requirements

1. The VDMS shall ensure that sales personnel can create a Market Sales Order (MSO) for vaccine orders within 5 minutes of receiving the order, with a success rate of 95% in a simulated context.
2. The VDMS shall facilitate healthcare providers in administering vaccines to eligible patients with an average processing time of 3 minutes per patient, achieving an efficiency rate of 90% during actual vaccine administration.
3. The VDMS shall achieve a user satisfaction score of at least 85%, as measured through feedback surveys, from logistics and shipping teams involved in coordinating vaccine shipments.

3.3 Performance Requirements

1. The vaccine management module shall create a Market Sales Order (MSO) within 5 minutes.
2. The Analytics & Decision support module (AD) shall create an alert if the business approval for the Market Sales Order (MSO) is still pending after 24 hours.
3. The Logistics & Shipment module (LS) shall generate Stock Transport Orders within 1 hour of Market Sales Order (MSO) creation.
4. The Analytics & Decision support module (AD) shall create critical alerts if stock movement between plants takes more than 48 hours to complete.
5. The Financial & Accounting (FA) module shall create electronic invoices for the Market Sales Order (MSO) within 24 hours.
6. The VDMS shall authenticate the user within 10 seconds.
7. Temperature monitoring interface shall trigger temperature checks for control sensors every 15 minutes to ensure continuous reliability in monitoring.
8. The VDMS shall adhere to specified functional allocation constraints, as outlined in the OpsCon.
9. The VDMS shall meet a maintainability mean downtime of 2 hours.
10. The VDMS shall meet a maintainability maximum downtime of 24 hours.
11. The VDMS shall have a mean time to repair of 2 hours.
12. The VDMS shall have an availability of 95%.
13. The VDMS shall have a reliability of 95%.

3.4 System Interface

1. The Vaccine Distribution and Management System (VDMS) shall have a Vaccine management (VM) Module.
2. The Vaccine Distribution and Management System (VDMS) shall have a Logistics and Shipment (LS) Module.
3. The Vaccine Distribution and Management System (VDMS) shall have a Financial & Accounting (FA) module.
4. The Vaccine Distribution and Management System (VDMS) shall have an Analytics & Decision Support (AD) Module.
5. The Analytics & decision Support (AD) Module shall be integrated into the Vaccine management (VM) Module.
6. The Analytics & decision Support (AD) Module shall be integrated into the Logistics and Shipment (LS) Module.
7. The Analytics & decision Support (AD) Module shall be integrated into the Financial & Accounting (FA) module.
8. The Vaccine management (VM) Module shall have an Inventory management interface.
9. The Vaccine management (VM) Module shall have a batch allocation interface.
10. The Vaccine management (VM) Module shall have a quality control interface.
11. The Vaccine management (VM) Module shall have a temperature monitoring interface.
12. The Logistics and Shipment (LS) Module shall have a route optimization interface.
13. The Logistics and Shipment (LS) Module shall have a shipment tracking interface.
14. The Logistics and Shipment (LS) Module shall have a goods receipt interface.
15. The Logistics and Shipment (LS) Module shall have a goods issue interface.
16. The Financial & Accounting (FA) module shall have a financial integration interface.
17. The Financial & Accounting (FA) module shall have a financial postings interface.
18. The Financial & Accounting (FA) module shall have an invoice generation interface.
19. The Financial & Accounting (FA) module shall have a financial integration interface.
20. The Analytics & decision Support (AD) module shall have a predictive analytics interface.
21. The Analytics & decision Support (AD) module shall have a reporting & dashboard interface.
22. The Analytics & decision Support (AD) module shall have an alerts and notification interface.
23. A dashboard interface in the Logistics and Shipment (LS) Module shall provide a visual representation of stock movements for monitoring by authorized personnel.
24. VDMS shall be accessible via mobile phone AND tablets for on the go access.

3.5 System Operations

1. Financial postings shall only be performed by the accounting staff in the Financial & Accounting (FA) module.
2. Temperature monitoring sensors in shipments shall communicate with the Logistics and Shipment (LS) Module.
3. Specialized vaccine storage facilities shall be connected to the VDMS via temperature control sensors.
4. GPS sensors in shipments shall communicate with the Logistics and Shipment (LS) Module.
5. When a shipment is rerouted, the Analytics & decision Support (AD) module shall create an alert for management review.
6. Vaccine expiry date monitoring shall trigger automated notifications for vaccine disposal.
7. The VDMS shall have a maximum time to repair of 24 hours.

3.6 System Modes and States

1. The Vaccine Distribution and Management System (VDMS) shall operate in normal operation mode.

2. The Vaccine Distribution and Management System (VDMS) shall operate in emergency mode.
3. The Vaccine Distribution and Management System (VDMS) shall operate in maintenance mode.
4. In response to power failures, the system shall switch to emergency mode.

3.7 Physical Characteristics

1. The VDMS hardware components shall adhere to weight constraints not exceeding 20 kilograms and dimension constraints of 50 cm x 50 cm x 20 cm, ensuring compatibility with standard storage and transportation facilities.
2. The VDMS hardware shall be constructed with durable and corrosion-resistant materials suitable for both indoor and outdoor installations, complying with industry standards for environmental resilience.
3. The VDMS hardware shall include prominent and durable system markings and nameplates, displaying essential information such as model number, serial number, and safety instructions.
4. The VDMS hardware components shall be designed to allow interchangeability without requiring specialized tools, ensuring flexibility for system upgrades, maintenance, and repairs.
5. The VDMS hardware shall be assembled and installed by certified technicians following industry-standard workmanship practices to ensure consistent quality and reliability.

3.8 Environmental Conditions

1. The VDMS shall operate within a natural environment that includes temperature variations ranging from -20°C to 40°C, humidity levels between 20% and 80%, and protection against exposure to rain, dust, and sand.
2. The VDMS components shall be designed to withstand induced environmental factors such as motion, shock, and electromagnetic interference within industry-standard thresholds.

3.9 System Security

1. The VDMS shall authenticate its users.
2. All data transmitted between system components and stored within the VDMS databases shall be encrypted using industry-standard cryptographic protocols.
3. The VDMS shall dynamically allocate access control permissions based on user roles.
4. The VDMS shall implement intrusion detection and prevention systems to monitor for and respond to suspicious activities, potential security breaches, or attempts to compromise the system.
5. The VDMS shall maintain an audit trail of all system activities.
6. The VDMS shall incorporate security measures to mitigate threats such as cyber-attacks and vandalism, complying with relevant legal and regulatory standards to ensure data confidentiality and system stability.

3.10 Information Management

1. The Vaccine Distribution and Management System (VDMS) shall encrypt all communications between elements of the system.
2. The VDMS shall backup its data to an external server.
3. The VDMS shall encrypt its data at rest.
4. Encrypted transmission protocols shall adhere to TLS 1.3 industry standard to secure data during transit.
5. The VDMS shall keep an audit log of all its communications.
6. The VDMS shall perform Data synchronization between the primary and backup systems to ensure that all critical data is mirrored and up-to-date.

7. The VDMS shall implement a comprehensive data classification system, categorizing information into levels of sensitivity and criticality.
8. The VDMS shall identify and protect proprietary information, trade secrets, and intellectual property.
9. The VDMS shall adhere to defined information retention policies, specifying the duration for which different types of information are retained.
10. The system shall automatically archive or purge information based on the above policies.
11. The VDMS shall define appropriate handling procedures, access controls, and encryption methods based on the data classification.

3.11 Policies and Regulations

1. The VDMS shall provide multilingual support for its user interface and documentation.
2. The VDMS shall adhere to all relevant privacy regulations and organizational policies governing the protection of personnel information.
3. The VDMS shall have the capability to generate and automatically submit reports to relevant health authorities as required by external regulatory obligations.

3.12 System Life Cycle Sustainment

1. The VDMS shall have the capability to generate and automatically submit reports to relevant health authorities as required by external regulatory obligations.
2. The VDMS life cycle sustainment plan shall include provisions for operational and depot-level support facilities, spares management, sourcing and supply chain logistics, provisioning of technical documentation, and ongoing support-personnel training, including initial cadre training and contractor-logistics support.

3.13 Packaging, Handling, Shipping, and Transportation

1. When vaccine is being transported, the shipment temperature shall continuously be monitored via sensors.

4 Verification

Functional Requirements Verification:

- **Approach:** Inspection and Demonstration
- **Methods:**
  - Review of vaccine order inputs and MSO creation process through the Vaccine Management (VM) module.
  - Live demonstration of AD flagging MSO for business approval.
  - Inspection of vaccine allocation processes for different markets.
  - Verification of stock movement notifications and procurement alerts by AD module.
  - Inspection of financial processes, including invoice creation.
  - Live demonstration of temperature excursion alerts and rerouting plans.

Usability Requirements Verification:

- **Approach:** User Feedback and Performance Testing
- **Methods:**
  - User surveys to assess sales personnel's ability to create MSO within the specified time.
  - Performance testing of the VDMS during simulated vaccine administration to evaluate efficiency.
  - Feedback surveys for logistics and shipping teams to assess user satisfaction.

Performance Requirements Verification:

- **Approach:** Testing and Monitoring
- **Methods:**
  - Performance testing for MSO creation, business approval, and stock order generation.
  - Monitoring of critical alerts and notifications in real-time.
  - Temperature monitoring system testing.
  - Authentication speed testing.
  - Continuous monitoring of system availability and reliability.

System Interface Verification:

- **Approach:** Inspection and Testing
- **Methods:**
  - Inspection of the integration between VDMS modules.
  - Testing of interfaces such as inventory management, batch allocation, and quality control.
  - Live demonstration of route optimization and shipment tracking.
  - Inspection of financial integration and invoicing interfaces.
  - Testing of predictive analytics and reporting interfaces.

System Operations Verification:

- **Approach:** Testing and Monitoring
- **Methods:**
  - Testing of financial posting permissions for the accounting staff.
  - Verification of communication between temperature sensors and the LS Module.
  - Inspection of specialized vaccine storage facility connections.
  - Verification of GPS sensor communication with the LS Module.
  - Testing of alert creation during shipment rerouting.

System Modes and States Verification:

- **Approach:** Testing and Inspection
- **Methods:**
  - Testing of normal, emergency, and maintenance modes.
  - Inspection of system response to power failures and transitions between modes.

Physical Characteristics Verification:

- **Approach:** Inspection and Testing
- **Methods:**
  - Inspection of hardware components for weight and dimension adherence.
  - Testing of hardware durability and corrosion resistance.
  - Verification of interchangeability of hardware components.

Environmental Conditions Verification:

- **Approach:** Testing and Monitoring
- **Methods:**
  - Testing of VDMS operation within specified temperature and humidity ranges.
  - Monitoring of environmental factors' impact on system components.

System Security Verification:

- **Approach:** Testing and Monitoring
- **Methods:**
  - Security testing for user authentication.
  - Encryption testing for data transmission and storage.
  - Testing of access control permissions and intrusion detection systems.

Information Management Verification:

- **Approach:** Testing and Inspection

- **Methods:**
  - Encryption testing for communication and data at rest.
  - Verification of data backup procedures.
  - Inspection of synchronization processes between primary and backup systems.

Policies and Regulations Verification:

- **Approach:** Inspection and Testing
- **Methods:**
  - Inspection of multilingual support in the user interface.
  - Testing of privacy regulation adherence.
  - Verification of reporting capabilities to health authorities.

System Life Cycle Sustainment Verification:

- **Approach:** Inspection and Testing
- **Methods:**
  - Inspection of reports generated for health authorities.
  - Testing of life cycle sustainment provisions, including spares management and ongoing support personnel training.

Packaging, Handling, Shipping, and Transportation Verification:

- **Approach:** Testing and Inspection
- **Methods:**
  - Continuous monitoring of shipment temperature during transportation.

A Assumptions and Dependencies

Assumptions

1. **Stakeholder Availability:** It is assumed that key stakeholders, including users from different modules and decision-makers, will be available for system demonstrations, reviews, and feedback sessions during the development and testing phases.
2. **Data Accuracy:** The accuracy of real-time data, including weather forecasts, traffic conditions, and temperature monitoring, is assumed to be reliable and up-to-date. Deviations in data accuracy could impact the effectiveness of predictive analytics and decision support.
3. **Infrastructure Stability:** The stability and reliability of the infrastructure, including network connectivity and server availability, are assumed to meet the operational needs of the VDMS. System performance and real-time monitoring rely on a stable IT infrastructure.
4. **Compliance with Regulations:** It is assumed that the VDMS will comply with relevant legal and regulatory standards regarding data security, privacy, and vaccine distribution. Changes in regulatory requirements could impact system functionality and processes.
5. **User Training:** Users are assumed to undergo adequate training to adapt to the new system functionalities, particularly for real-time temperature monitoring, predictive analytics, and emergency response procedures.
6. **Equipment Compatibility:** The compatibility of GPS sensors, temperature control sensors, and other hardware components with the VDMS is assumed. Any changes or incompatibility could affect the tracking, monitoring, and overall functionality of the system.

Dependencies

1. **External Data Sources:** The VDMS is dependent on external data sources, such as weather forecasts and traffic conditions. Changes or disruptions in these external data sources could impact the accuracy of predictive analytics and decision support.
2. **Network and Communication Infrastructure:** Dependencies on network infrastructure for communication between modules, real-time data transfer, and system monitoring. Any issues with the network could affect system responsiveness and data synchronization.

3. **Manufacturing Plant Operations:** The VDMS is dependent on the timely and accurate operations of manufacturing plants for vaccine production and allocation. Delays or disruptions in manufacturing processes could impact inventory management and distribution.
4. **Availability of Maintenance Personnel:** The availability of maintenance personnel is crucial for system updates, patches, and addressing any issues during maintenance mode. The lack of availability could lead to delays in maintaining system integrity.
5. **Legal and Regulatory Changes:** Dependencies on legal and regulatory frameworks for vaccine distribution. Changes in regulations may necessitate updates to the system to ensure compliance.
6. **Vendor Support:** Dependencies on the support and updates provided by vendors for hardware components, sensors, and other system elements. Lack of vendor support could impact the maintainability and performance of the VDMS.
7. **User Cooperation:** The effectiveness of the VDMS relies on the cooperation of users in adhering to new procedures and utilizing the system optimally. Resistance to change or lack of user cooperation could impact system efficiency.
8. **Global Health Conditions:** Dependencies on global health conditions, especially during emergency scenarios. Unexpected events, such as pandemics or geopolitical factors, could impact vaccine distribution patterns and emergency response.

B Acronyms and Abbreviations

GPS = Global Positioning System
TLS = Transport Layer Security

Any other acronyms or abbreviations used within this document were defined when initially introduced therefore, no exceptions noted.