SE627 Group project

Team – 3

Rishabh Pandey

Ethan Mil

Operational Concept Document Template from

ISO/IEC/IEEE 29148:2011

October 2023

1 Contents

2 Scope

2.1 Identification

This section outlines the scope of this Operational Concept (OpsCon) document in the context of the project "Logistics Operations of COVID-19 Vaccine." 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.

2.2 Document Overview

This section provides an overview of the key purposes, audience, security and privacy considerations, and the outline of this Operational Concept (OpsCon) document, within the context of the proposed project.

Purposes and Motivations: The primary purposes of this OpsCon document are to articulate the user's needs for and expectations of the proposed system. This involves defining the requirements and functionalities that the system should deliver to meet these needs.

Intended Audience: The audience for this OpsCon document includes the following groups:

Users: Represent various stakeholders involved in the COVID-19 vaccine distribution process, such as healthcare professionals, government agencies, and logistics personnel. Users may refer to this document to ensure that their specific needs and requirements have

been accurately represented by their designated representatives. This document provides them with an opportunity to validate whether the supplier's understanding of their requirements aligns with their expectations.

Acquirers: Often governmental or regulatory bodies, play a pivotal role in ensuring that the distribution of the COVID-19 vaccine aligns with public health and regulatory standards. Entities like the Food and Drug Administration (FDA) could be considered as acquirers. They use this document to gain a comprehensive understanding of the user's needs and requirements, facilitating transparent communication between all parties. This ensures that the project remains compliant with all necessary regulations and standards.

Suppliers: Suppliers refer to the organizations responsible for developing and implementing the software architecture for vaccine distribution. These suppliers leverage this OpsCon document as a foundational reference for various system lifecycle activities. It serves as a blueprint to guide their actions and decisions during the project. Additionally, it assists in familiarizing new team members with the problem domain and the specific system to which the OpsCon applies. In this scenario, a technology company might serve as the supplier for the software solution.

2.3 System Overview

The proposed software system in question aims to refine the logistics operations for the distribution of Pharma company XYZ's COVID-19 vaccine. The primary purpose of this system is to ensure the efficient and secure distribution of the COVID-19 vaccine globally through the organization’s two manufacturing plants in the US and one in EU. Key stakeholders include Pharma company XYZ, user agencies, supplier organizations, support agencies, and certifiers or certifying bodies. The primary purpose of this system is to orchestrate the entire logistics chain for distributing the COVID-19 vaccine. It encompasses activities ranging from manufacturing to shipment and delivery, all with a keen focus on maintaining the vaccine's quality and integrity throughout the process. The system aims to ensure the timely and accurate delivery of the vaccine to its intended destinations, adhering to the cold chain requirements to guarantee its efficacy.

3 Referenced Documents

3.1. 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

3.2. European Commission Guidelines:

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

Date: 19 March 2015

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

4 Current System or Situation

Pharma Company XYZ has successfully developed its COVID-19 vaccine and is now aiming to create a software architecture for the global distribution of this vaccine. The current system for vaccine distribution primarily relies on manual processes, with limited visibility into the supply chain, posing challenges in ensuring the vaccine's safety and timely delivery.

4.1 Background, Objectives, and Scope

Pharma Company XYZ has its vaccine manufacturing plants spread across North America and Europr, with two located in the United States and one in the European Union. The distribution responsibilities are divided, with the U.S. plants managing vaccine distribution across the Americas, and the EU plant handling distribution across the APAC and EMEA regions.

Objectives

The primary objectives of the current system are to fulfill vaccine requirements while maintaining the integrity of the vaccine during distribution, ensuring compliance with regulatory and quality standards, and facilitate timely and accurate financial transactions as these objectives are essential to meet the demand for the COVID-19 vaccine globally.

Scope

The scope of the current system extends from vaccine production to final delivery. It encompasses processes such as manually creating Market Sales Orders (MSOs), integrity checks, batch and inventory allocation, inventory movements between plants, accounting, and financial posting. Additionally, it includes manually creating technical documents such as creating Stock Transport Orders, outbound deliveries for tracking shipments, goods

issue and receipt documents for actual stock movement, and account documents for financials.

4.2 Operational Policies and Constraints

Operational policies and constraints governing the current system include adherence to international cold chain logistics regulations and quality standards. There are specific temperature requirements that must be maintained to ensure the vaccine's efficacy during transit.

Policies:

- Compliance with international cold chain logistics regulations.
- Adherence to quality standards for vaccine production and distribution.
- Secure and timely financial transactions for vaccine sales.

Constraints:

- Strict temperature control throughout the distribution process.
- Compatibility and interoperability among software components.
- Timely and accurate financial postings in line with international standards.

4.3 Description of the Current System or Situation

The current system for vaccine distribution relies heavily on manual processes and lacks the presence of any specific software or technical system. All essential information and data entries are manually recorded, often in physical record files and journals. These manual records are subsequently imported into Excel spreadsheets for tracking and management purposes.

Operational Environment: The current system operates within the pharmaceutical industry's regulatory framework, the primary objective of which is ensuring the safety and quality of vaccines during distribution. The cold chain logistics requirements dictate specific temperature conditions for vaccine transportation.

System Elements: Major elements include vaccine manufacturing plants, sales department, inventory management, financial departments, and logistics personnel.

Interfaces: Manual recordkeeping interfaces exist between the sales department in the current system, enabling the creation of Market Sales Orders (MSOs) and initiation of the distribution process.

Capabilities and Features: The current system can initiate MSOs, track inventory movements, generate financial documents, and handle financial postings.

Temperature Monitoring: Temperature readings are not captured in real-time, and there is no provision for capturing temperature excursions.

Regulatory Compliance: The system is designed to meet international regulatory standards, but improvements are required to ensure full compliance and real-time temperature monitoring.

Financial Transactions: The system is capable of financial postings but lacks integration with a virtual financial bookkeeping plant for vaccine shipment initiation.

4.4 Modes of Operation for the Current System or Situation

The current system primarily operates in a standard operational mode, focusing on vaccine distribution. However, it lacks distinct modes such as maintenance, training, and emergency, which may be necessary for ensuring the vaccine's safety and integrity.

4.5 User Classes and Other Involved Personnel

User classes within the current system include the sales department, manufacturing plant personnel, logistics and shipping staff, accounting and financial personnel, and customers who receive the vaccine. Other personnel involved may include regulatory bodies overseeing cold chain logistics and quality compliance.

4.6 Support Environment

The proposed system will utilize SAP as the technical document creation software and incorporate a custom tool to streamline vaccine distribution. Additionally, it will integrate real-time temperature monitoring devices and predictive analytics capabilities to enhance decision-making.

5 Justification For and Nature of Changes

5.1 Justification for Changes

The development of the proposed software architecture for the global distribution of Pharma company XYZ's COVID-19 vaccine is necessitated by several factors:

User Needs and Objectives

The current system fails to meet the escalating user demands for efficient vaccine distribution. Users require a streamlined process from Market Sales Order (MSO) creation to delivery, as well as real-time temperature monitoring, predictive analytics, and financial integration. The proposed system addresses these needs.

Current System Limitations:

The deficiencies in the current manual system are evident in its inability to provide real-time data capture of temperature readings, respond to temperature excursions, or ensure efficient financial processes. These limitations hinder Pharma company XYZ's ability to deliver vaccines securely and timely.

Regulatory Compliance

The proposed system aligns with stringent cold chain logistics FFDA (Food and Drug Administration) regulation (21 CFR 205.50) to ensure the vaccine's efficacy during distribution. The current system lacks the capabilities to maintain temperature conditions, making it non-compliant with regulatory standards.

5.2 Description of Changes

I) Capability Changes

The system introduces a comprehensive Vaccine Management Module (VM) that includes Inventory Management, Batch Allocation, Quality Control, and Temperature Monitoring. A Logistics and Shipment Module (LS) is incorporated, which comprises Route Optimization, Shipment Tracking, Goods Receipt, and Goods Issue. Additionally, a Financial and Accounting Module (FA) is established to ensure financial integration and secure financial postings. An Analytics and Decision Support Module (AD) is added, offering Predictive Analytics, Reporting and Dashboard, and Alerts and Notifications.

II) System Processing Changes

The system transitions from manual processes to automated workflows. Data transformation processes are reengineered to facilitate real-time temperature data capture and predictive analytics, resulting in more informed decision-making.

III) Interface Changes

The system introduces seamless interfaces between modules, allowing VM to communicate with LS for vaccine shipment initiation. LS interacts with FA for financial integration and initiates shipments from a virtual financial bookkeeping plant. Real-time temperature data sharing and predictive analytics enhance decision support across all modules. The system is also portable to mobile and tablet versions for ease of use.

IV) Operational Changes

User operational policies and procedures are redefined to align with the new system's capabilities. Users are trained to work within the automated system, enabling them to respond efficiently to real-time data.

V) Support Changes

The transition to the new system demands a shift in support requirements. The support environment must adapt to help with the expanded functionalities and address any technical issues that may arise.

5.3 Priorities Among Changes

Essential Features

The highest priority is assigned to ensuring the successful implementation of the Vaccine Management Module (VM) and Logistics and Shipment Module (LS). These modules are critical for secure vaccine distribution, real-time monitoring, and financial integration.

Desirable Features

Predictive analytics within the Analytics and Decision Support Module (AD) is considered desirable. While not essential, it enhances the system's capabilities and decision support.

Optional Features

Certain features like Reporting and Dashboard in AD are optional. These features provide additional value but are not mandatory for the core functionality.

5.4 Changes Considered but Not Included

Additional features, such as geospatial mapping for route optimization, were considered but not included due to budget constraints. While they could enhance the system, the core functionality takes precedence.

5.5 Assumptions and Constraints

The assumption is made that the vaccine developed has passed all clinical trials and obtained the appropriate labelling license Additionally, the System's workload will increase due to heightened demand for the COVID-19 vaccine, justifying the need for higher system performance and scalability.

6 Concepts for the Proposed System

6.1 Background, Objectives, and Scope:

The proposed system aims to revolutionize the distribution of Pharma company XYZ's COVID-19 vaccine. The primary objectives of the proposed system are to automate vaccine distribution, maintain vaccine integrity, ensure regulatory compliance, enhance financial processes, and provide predictive analytics capabilities. These objectives aim to meet the escalating global demand for the COVID-19 vaccine and improve operational efficiency. The scope of the proposed system encompasses the entire logistics chain, from vaccine production to final delivery. It includes activities such as automatic initiation of

Market Sales Order (MSO) creation, integrity checks, batch and inventory allocation, inventory movements, financial processes, temperature monitoring, predictive analytics, decision support, and automatic system logs creation. The system will support a virtual financial bookkeeping plant, adhere to regulatory standards, and ensure secure, timely vaccine distribution.

6.2 Operational Policies and Constraints

In addition to the general operational policies and constraints outlined in the previous section, this subsection addresses the specific cold chain requirements mandated by 21 CFR 205.50. These regulations are vital to ensuring the safe storage and distribution of prescription drugs, including the COVID-19 vaccine.

Operational Policies:

- Prescription drugs, including the COVID-19 vaccine, shall be stored and handled in strict compliance with the cold chain regulations outlined in 21 CFR 205.50.
- All prescription drugs must be maintained at appropriate temperatures, as specified in their labeling or official compendium requirements, such as the United States Pharmacopeia/National Formulary (USP/NF).
- Suitable temperature and humidity recording equipment, devices, and logs shall be utilized to document the proper storage of prescription drugs.

Operational Constraints - Cold Chain Security & Recordkeeping:

- Facilities used for storing prescription drugs must comply with 21 CFR 205.50, ensuring they are of suitable size, design, and construction to facilitate proper operations, temperature control, and security.
- Access to areas where prescription drugs are stored shall be limited to authorized personnel to prevent unauthorized entry.
- The facilities used for vaccine distribution shall be equipped with an alarm system to detect entry after hours and a security system to provide protection against theft and diversion, including tampering with electronic records.
- All incoming and outgoing shipments of prescription drugs shall undergo rigorous inspection to verify their identity, integrity, and compliance with storage requirements.
- Wholesale drug distributors shall establish and maintain records as required by 21 CFR 205.50. These records shall include information about the source of drugs, their identity and quantity, and the dates of receipt and distribution.
- Inventories and records, including those related to cold chain compliance, shall be made available for inspection by authorized Federal, State, or local law enforcement officials for a period of 3 years, as stipulated by the regulation.

6.3 Description of the Proposed System

The proposed Vaccine Distribution and Management System (VDMS) will operate within a highly regulated environment in the pharmaceutical industry, with a particular emphasis on cold chain compliance.

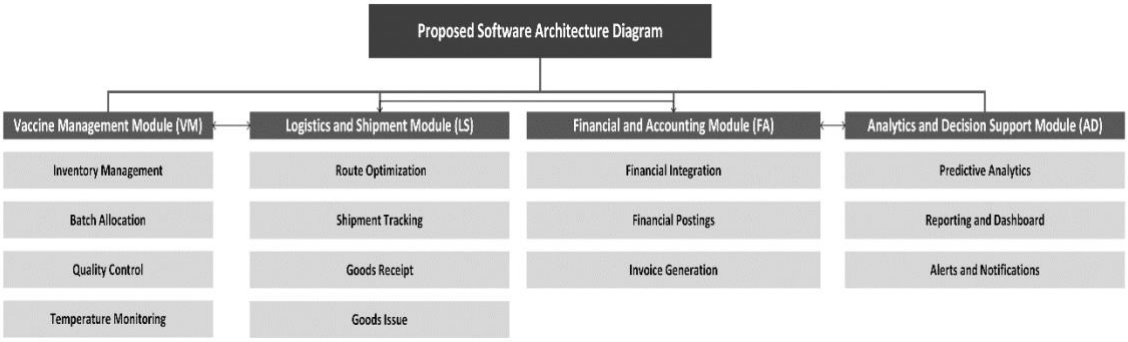

Figure 1. Proposed VDMS System overview

This section provides a detailed description of the VDMS, encompassing various facets

Major System Elements and Interconnections:

VDMS will be comprised of four interconnected modules:

- Vaccine Management (VM): This module will initiate vaccine shipments and conduct integrity checks. VM will interface with Logistics and Shipment (LS) for shipment initiation, Financial and Accounting (FA) for financial integration, and Analytics and Decision Support (AD) for real-time temperature data sharing and predictive analytics.
- Logistics and Shipment (LS): LS will be responsible for coordinating vaccine shipments and ensuring they align with the cold chain regulations. It will communicate with VM to initiate shipments and interface with FA for financial integration.
- Financial and Accounting (FA): This module will be designed to integrate financial processes with vaccine distribution. It will support financial bookkeeping and ensure accurate financial postings.
- Analytics and Decision Support (AD): AD will leverage real-time temperature data via sensors in shipment packages to provide predictive analytics capabilities for informed decision-making.

Capabilities and Functions

VDMS will offer a range of capabilities and functions that ensure compliance with regulatory standards and efficient vaccine distribution:

- Users and Access Controls: The system incorporates user friendly graphical user interface and role-based access controls, and multifactor authentications to ensure data security.

- Automated MSO Creation: The system streamlines Market Sales Order (MSO) creation within 5 minutes of receiving a vaccine order, seek business approval within a timeframe of 24 hours to confirm the integrity of the order.
- Inventory Allocation and Batch Allocation: Custom tools in the vaccine and the logistics modules aid in the allocating vaccines from the appropriate plant based on geographic locations. Subsequently, within a timeframe of 1 hour, the system will generate Stock Transport Orders to move inventory between plants.
- Stock Movements: VDMS will execute stock movements notifications, including procurement and inventory movements alerts. If inventory movement is not completed within 48 hours, the system will raise critical alerts for that particular order.
- Procurement and Accounting: The financial module will have custom creation tools to assist accounting staff with accounting operations to ensure accurate financial postings in the system for each order.
- Goods Shipment from Financial Bookkeeping Plant: Vaccine shipments will be dispatched from the financial bookkeeping plant to facilitate proper routing.
- Temperature Excursion Management: The system will continuously monitor temperature via sensors placed in shipments during vaccine transportation and automatically raise alerts to reroute shipments in the event of a temperature excursion to prevent further vaccine loss.
- Vaccine Expiration Tracking: The system will track expiration dates of vaccine batches to ensure the safety and efficacy of administered vaccines.
- Predictive Analytics Capabilities: Users will have access to predictive analytics tools with variables like geographic location & distribution, demand & supply among users, past historic trends for strategic vaccine manufacturing.
- Distribution Alerting and Notification: VDMS will automatically alert all stakeholders when deviations occur in the vaccine distribution process and recommend suggestions.
- Invoicing and Financial Postings: Within 24 hours after vaccine delivery, electronic invoice generation by the system will be executed. The FM module will display these invoices according to order received & payment due hierarchy.
- Vaccine Eligibility Verification: VDMS will have the capability to ensure that only eligible individuals receive vaccines, preventing fraud or misuse by verifying vaccine eligibility based on data entered by healthcare providers and government guidelines.
- Vaccine Event Reporting: VDMS will ensure timely reporting to regulatory authorities, prompting appropriate follow-up actions enabling healthcare providers to report any adverse events or reactions related to the vaccines.

6.4 Modes of Operation

VDMS will operate in various modes, ensuring adaptability to different scenarios:

- Regular Mode: This mode will handle standard vaccine distribution.
- Emergency Mode: In case of unforeseen crises such as power outages, the system will switch to emergency mode to ensure timely response. It will recalibrate distribution plans, reroute shipments, and push automatic alerts to all stakeholders, including authorities.
- Maintenance Mode: Routine system upkeep to check backup systems and ensure data integrity.

6.5 User Classes and Other Involved Personnel:

VDMS will involve various user classes and personnel:

- Sales Personnel: Responsible for initiating vaccine orders and MSO creation.
- Manufacturing Plant Staff: Will manage batch allocation and inventory movements.
- Logistics and Shipping Teams: Will coordinate vaccine shipments and ensure cold chain compliance.
- Accounting and Financial Personnel: Will oversee financial processes, invoices, and financial postings.
- Healthcare Provider: Responsible for administering vaccines to eligible patients.
- Eligible Patients: The end-users of the vaccine will be integral to the system.
- Executive Managers and Policymakers: May not directly interact with the system but will significantly influence its operations and decision-making.

6.6 Support Environment

The support environment for VDMS will encompass elements such as support agencies, facilities, equipment, maintenance schedules, storage, distribution methods, and supply methods. This environment will be critical to maintaining the system's integrity and efficiency.

Provisions for Safety, Security, Privacy, Integrity, and Continuity of Operations in Emergencies:

- VDMS will remotely monitor and respond to temperature excursions via sensors during transportation & storage at facilities to safeguard vaccine safety & integrity.
- The system will enforce access controls, data encryption, and tamper-evident technology for security.
- Data encryption and secure transmission protocols will protect sensitive information.
- VDMS will employ checksums and digital signatures to ensure data integrity and minimize data corruption.

Logistics Requirements to Support the System:

- Certified & vetted logistics partners with cold chain expertise.

- Specialized storage facilities with temperature control systems.
- Real-time temperature monitoring devices and sensors.
- Regular equipment and facility maintenance.
- Dedicated cold storage rooms with backup power sources.
- Meticulous planning of delivery routes and transport modes via AD module.
- Just-in-time inventory management for minimizing excess stock and enabling efficient distribution.

7 Operational Scenarios

1. Scenario 1:

Background: In this operational scenario, the VDMS operates in its regular mode, handling standard vaccine distribution.

Pre-Conditions: The following pre-conditions need to be met for this operational scenario:

- All equipment is operational.
- Vaccine orders have been received.
- Inventory is available for distribution.

Post-Conditions: The following post-conditions are met for this operational scenario:

- Successful vaccine distribution.
- Vaccine inventory updated.
- Financial records are updated.

Operational Flow:

Sales personnel review the Market Sales Orders (MSOs) for vaccine orders. MSOs are reviewed for integrity, batch allocation, and business approval within the Vaccine Management (VM) module. Inventory allocation is carried out based on geographic locations. Stock movements between plants, procurement, and accounting operations are executed within the Financial and Accounting (FA) module. Vaccine shipments are dispatched from the financial bookkeeping plant to ensure proper routing. Users will be able to track the vaccine shipments in real time via the LS module. Temperature during vaccine transportation and storage is continuously monitored via sensors. Invoices and financial postings are executed after vaccine delivery within 24 hours. Automatic alerts are sent to stakeholders in case of deviations. All data is logged by the system which will be available to users in the AD module for measuring performance and generating reports.

2. Scenario 2:

Background: In this operational scenario, the VDMS switches to emergency mode in response to unforeseen crises to ensure timely and adaptive vaccine distribution.

Pre-Conditions: The following pre-conditions need to be met for this operational scenario:

- Emergency mode is activated.
- Emergency distribution plans are in place.

Post-Conditions: The following post-conditions are met for this operational scenario:

- Emergency vaccine distribution executed with precision.
- Rerouted shipments reach affected areas promptly.
- Automatic alerts sent to all stakeholders, including authorities.

Operational Flow:

When a crisis is detected, the VDMS is switched to emergency mode, triggering a series of actions to ensure timely and adaptive response. The system's algorithms immediately assess the crisis situation. Urgent needs are calculated based on multiple factors, including population density, infection rates, and the availability of medical facilities. Areas with the highest urgency receive the highest priority. The system utilizes route optimization algorithms. It identifies alternative routes by analyzing real-time traffic data, road closures, and transportation options. Alternative routes may include using different transportation modes, such as air cargo or emergency ground convoys. The VDMS continually monitors the progress of shipments and road conditions. If an alternative route becomes more efficient due to changing circumstances, the system will dynamically adjust routes in real-time to ensure timely delivery. The system establishes communication channels with local authorities and government agencies to coordinate emergency response efforts effectively. This communication is crucial for obtaining real-time updates on crisis situations and aligning distribution efforts with the latest information.

3. Scenario 3:

Background: In this operational scenario, the VDMS undergoes routine system upkeep to check backup systems and ensure data integrity.

Pre-Conditions: The following pre-conditions need to be met for this operational scenario:

- Maintenance mode is initiated.

- Backup systems are available.

Post-Conditions: The following post-conditions are met for this operational scenario:

- System integrity and data security ensured.
- Backup systems checked and verified.
- System returns to regular mode after maintenance.

Operational Flow:

Maintenance mode is scheduled during off-peak hours to minimize disruption. The stakeholders are informed via alerts about the initiation of maintenance mode. The system temporarily switches to maintenance mode and initiates thorough checks of backup systems by simulating various failure scenarios. It verifies the functionality of failover mechanisms, ensuring they can seamlessly take over in case of a primary system failure. During maintenance, the system conducts comprehensive checks on data integrity. It verifies the accuracy and consistency of all stored information by performing checksums and data consistency checks. Failover mechanisms are tested through controlled system failures, and the transition to backup systems is validated to ensure minimal downtime. Data synchronization is performed between the primary and backup systems to ensure that all critical data is mirrored and up to date. This includes the use of data replication technologies to maintain data consistency. Routine security patches and updates are applied during maintenance to address potential vulnerabilities and enhance system security. These updates are validated in subsequent tests to ensure they do not introduce new issues. A complete system health check is conducted, including performance optimization and resource allocation. The system performs stress tests to evaluate its capacity to handle peak loads. Once all maintenance tasks are successfully completed, logged, and verified, the VDMS is switched back to regular mode, ensuring no disruption to ongoing vaccine distribution activities.

8 Summary of Impacts

In this section, we will describe the operational and organizational impacts of the proposed Vaccine Distribution and Management System (VDMS) on various stakeholders, both during its operation and the development phase. This information is essential for planning and preparing for the changes that the VDMS will bring about.

8.1 Operational Impacts

Operational Impacts on Users:

Users will experience changes in the procedures for vaccine distribution. The VDMS will streamline the Market Sales Order (MSO) creation process, which will impact how vaccine orders are initiated and managed. Furthermore, users will need to adapt to using new data

sources, particularly for real-time temperature monitoring and predictive analytics. This may require training and a shift in their data input practices.

Operational Impacts on Support and Operations/Maintenance Organizations:

Support organizations will need to establish interfaces with primary and alternate computer operating centers to ensure the seamless operation of the VDMS. Operations and maintenance organizations may experience changes in their operational budget due to the implementation of the VDMS. This includes costs associated with maintaining real-time temperature monitoring devices, route optimization, and emergency response capabilities. Additionally, the introduction of the VDMS will bring about changes in operational risks. Support and operations/maintenance organizations will need to assess and mitigate risks related to data security, system reliability, and emergency response.

8.2 Organizational Impacts

Organizational Impacts on Users:

Users will have to undergo a modification of responsibilities, particularly in how they initiate vaccine orders, monitor real-time data, and respond to emergency situations. Users will also require training or retraining to adapt to the new system's functionalities, including real-time temperature monitoring and predictive analytics.

Organizational Impacts on Development and Support/Maintenance Organizations:

Development and support/maintenance organizations may need to add or eliminate job positions to manage the VDMS effectively. This could include hiring data analysts or specialists in cold chain logistics. Subsequently, the introduction of the VDMS may result in changes in the numbers, skill levels, position identifiers, or locations of personnel in development and support/maintenance organizations.

8.3 Impacts During Development

Impacts During Development on Users, Development, and Support/Maintenance Agencies:

Users and support organizations will actively participate in reviews and demonstrations to evaluate initial operating capabilities and evolving versions of the system. This will help in refining the system to meet their needs. Additionally, during the development phase, there may be parallel operation of the new VDMS and the existing systems. This allows for a smooth transition and ensures that the new system meets operational requirements. System testing during development may lead to operational impacts. Users, development, and support/maintenance agencies should be prepared for potential disruptions and changes in their operational procedures as the new system is tested and refined.

9 Analysis of the Proposed System

9.1 This Section is skipped as per the instruction of the instructor.

A. Acronyms and Abbreviations

OpsCon: Operational Concept Document

MSO: Market Sales Order

VDMS: Vaccine Distribution and Management System

CDC: Centers for Disease Control and Prevention

FDA: Food and Drug Administration

EMEA: Europe, the Middle East, and Africa

APAC: Asia-Pacific

CFR: Code of Federal Regulations

USP/NF: United States Pharmacopeia/National Formulary

B. Glossary

Vaccine Distribution and Management System (VDMS): The proposed system for streamlining the distribution of Pharma Company XYZ's COVID-19 vaccine, ensuring efficiency, regulatory compliance, and data-driven decision-making.

Market Sales Order (MSO): An order for vaccine products created through the VDMS, initiating the vaccine distribution process.

CDC (Centers for Disease Control and Prevention): A national public health agency in the United States responsible for protecting public health and safety through the control and prevention of diseases, injuries, and disabilities.

FDA (Food and Drug Administration): A federal agency of the United States Department of Health and Human Services responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter medications, vaccines, biopharmaceuticals, blood transfusions, radiation-emitting devices, and veterinary products.

EMEA (Europe, the Middle East, and Africa): A geographical region representing a wide area that includes countries from Europe, the Middle East, and Africa.

APAC (Asia-Pacific): A geographical region representing countries from Asia and the Pacific regions.

CFR (Code of Federal Regulations): The codification of the general and permanent rules and regulations published in the Federal Register by the executive departments and agencies of the federal government of the United States.

USP/NF (United States Pharmacopeia/National Formulary): A publication that contains standards for pharmaceuticals, dietary supplements, and other healthcare practices in the United States