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MASTER'S THESIS

Towards the attainment of an Academic Master's Degree In
« Entrepreneurship And Project Management »

Contributing to the Improvement of Cold Chain Risk Management in Pharmaceutical Distribution.

Case Study: Central Pharmacy of Hospitals, Annaba

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ABSTRACT

In the Algerian public pharmaceutical distribution sector, managing the cold chain is essential to ensure drug integrity and patient safety. This study explores this challenge at the Central Pharmacy of Hospitals (PCH) Annaba Annex, a facility facing infrastructural constraints, high inbound stock volumes, and long-distance transport dependencies. The research aims to identify cold chain vulnerabilities and propose a transition from reactive crisis management to proactive Quality Risk Management.

This study adopts a qualitative approach based on semi-structured interviews analyzed through NVivo thematic analysis. To support the evaluation and prioritization of identified risks, qualitative findings were complemented by risk assessment tools, namely the Ishikawa diagram and the Failure Mode and Effects Analysis (FMEA) matrix.

The findings highlight major logistical risks within a highly constrained physical environment. Externally, the facility suffers from a thermal traceability "blind spot" during upstream transport. Internally, severe spatial congestion and frequent cold room door openings compromise temperature stability. Furthermore, the facility's risk governance lacks maturity: the ISO 9001:2015 certification was not renewed, formal Standard Operating Procedures (SOPs) are absent, and monitoring remains strictly reactive.

Ultimately, these root causes underscore the urgent need for a structured Corrective and Preventive Action (CAPA) plan to sustainably strengthen cold chain resilience.

Keywords: Cold Chain, Risk Management, FMEA, CAPA, Pharmaceutical Distribution.

RÉSUMÉ

Dans le secteur public algérien de la distribution pharmaceutique, la gestion de la chaîne du froid est essentielle pour garantir l'intégrité des médicaments et la sécurité des patients. Cette étude examine cette problématique au niveau de l'Annexe de la Pharmacie Centrale des Hôpitaux (PCH) d'Annaba, un établissement confronté à des contraintes d'infrastructure, à des volumes élevés de stocks entrants et à une forte dépendance au transport longue distance. La recherche vise à identifier les vulnérabilités de la chaîne du froid et à proposer une transition d'une gestion réactive des crises vers une gestion proactive des risques qualité.

Cette étude adopte une approche qualitative fondée sur des entretiens semi-directifs analysés à l'aide d'une analyse thématique réalisée avec le logiciel NVivo. Afin de soutenir l'évaluation et la hiérarchisation des risques identifiés, les résultats qualitatifs ont été complétés par des outils d'analyse des risques, notamment le diagramme d'Ishikawa et la méthode AMDEC (Analyse des Modes de Défaillance, de leurs Effets et de leur Criticité).

Les résultats mettent en évidence d'importants risques logistiques dans un environnement fortement contraint. Sur le plan externe, l'établissement souffre d'un « angle mort » en matière de traçabilité thermique durant le transport amont. Sur le plan interne, une congestion importante des espaces et les ouvertures fréquentes des chambres froides compromettent la stabilité de la température. De plus, la maturité du système de gestion des risques demeure limitée : la certification ISO 9001:2015 n'a pas été renouvelée, les procédures opératoires normalisées (SOP) sont absentes et le suivi reste essentiellement réactif.

Enfin, ces causes profondes soulignent la nécessité urgente de mettre en œuvre un plan d'Actions Correctives et Préventives (CAPA) afin de renforcer durablement la résilience de la chaîne du froid.

Mots-clés : Chaîne du froid, Gestion des risques, AMDEC, NVivo, CAPA, Distribution pharmaceutique.

الملخص

في قطاع التوزيع الصيدلاني العمومي في الجزائر، تُعد إدارة سلسلة التبريد أمراً أساسياً لضمان سلامة الأدوية والحفاظ على صحة المرضى. تتناول هذه الدراسة هذا التحدي على مستوى ملحقة الصيدلية المركزية للمستشفيات بعنابة، وهي مؤسسة تواجه قيوداً في البنية التحتية، وارتفاعاً في حجم المخزون الوارد، واعتماداً كبيراً على النقل لمسافات طويلة. وتهدف الدراسة إلى تحديد مواطن الضعف في سلسلة التبريد واقتراح الانتقال من إدارة تفاعلية للأزمات إلى إدارة استباقية لمخاطر الجودة.

تعتمد هذه الدراسة على منهجية نوعية قائمة على مقابلات شبه موجهة تم تحليلها باستخدام التحليل الموضوعاتي بواسطة برنامج NVivo. ولدعم عملية تقييم المخاطر وترتيب أولوياتها، تم استكمال النتائج النوعية بأدوات تحليل المخاطر، وهي مخطط إيشيكاوا (Ishikawa) وتحليل أنماط الإخفاق وتأثيراتها ودرجة خطورتها (FMEA).

أظهرت النتائج وجود مخاطر لوجستية مهمة ضمن بيئة تشغيلية شديدة القيود. فمن الناحية الخارجية، تعاني المؤسسة من «فجوة في التتبع الحراري» أثناء مرحلة النقل. أما داخلياً، فإن الاكتظاظ المكاني وعمليات فتح أبواب غرف التبريد بشكل متكرر يؤثران سلباً على استقرار درجة الحرارة. كما أن نظام إدارة المخاطر لا يزال محدود النضج، حيث لم يتم تجديد شهادة ISO 9001:2015، وتغيب إجراءات التشغيل المعيارية (SOPs)، بينما يظل نظام المراقبة قائماً على التدخل بعد وقوع المشكلات.

وفي النهاية، تؤكد هذه الأسباب الجذرية الحاجة الملحة إلى تطبيق خطة إجراءات تصحيحية ووقائية (CAPA) من أجل تعزيز مرونة سلسلة التبريد بشكل مستدام.

الكلمات المفتاحية:. سلسلة التبريد ، إدارة المخاطر، التوزيع الصيدلاني، تحليل أنماط الفشل وتأثيراته (FMEA/AMDEC) ، الإجراءات التصحيحية والوقائية .(CAPA)

GRATITUDE

First and foremost, I express my deepest gratitude to ***Allah*** *for His infinite grace, for giving me the strength to persevere, and for illuminating my path throughout this journey.*

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LIST OF ABBREVIATION

- **3PLs:** Third-Party Logistics providers
- **5RM:** 5th Military Regions
- **AI:** Artificial Intelligence
- **ANPP**: National Agency of Pharmaceutical Products
- **ATS:** Automatic Transfer Switch
- **CAC:** Cancer Center
- **CAPA:** Corrective and Preventive Action
- **CHU:** University Hospital Centers
- **DISI:** IT and Information Systems Directorate
- **DML:** Logistics Directorate
- **DSP:** Direction de la Santé et de la Population
- **DTR:** Technical and Regulatory Directorate
- **EEFO:** Earliest Expiry-First Out
- **EHS:** Etablissement Hospitalier Spécialisé
- **E.P.H:** Etablissement Public Hospitalier
- **EPIC:** Public Establishment with an Industrial and Commercial Character
- **E.P.S.:** Etablissement Public de Santé
- **EU:** European Union
- **FDA:** U.S. Food and Drug Administration
- **FEFO:** First Expired, First Out
- **FIFO:** First In-First Out
- **FMEA:** Failure Mode, Effects, and Criticality Analysis
- **GDP**: Good Distribution Practices
- **GMP:** Good Manufacturing Practices
- **GSP:** Good Storage Practice
- **HACCP:** Hazard Analysis and Critical Control Points
- **ICH:** International Council for Harmonization
- **IoT:** Internet of Things (Internet des Objets)
- **ISO:** International Organization for Standardization
- **KPIs:** Key Performance Indicators

- **KRIs:** Key Risk Indicators
- **LSTM:** Long Short-Term Memory
- **MOPH:** Ministry of Public Health
- **NVivo:** Logiciel d'analyse qualitative
- **ORSEC:** Organisation de la Réponse de Sécurité Civile
- **PCH:** Central Pharmacy of Hospitals
- **QBD:** Quality by Design
- **QDA:** Qualitative Data Analysis
- **QMS:** Quality Management System
- **QRM:** Quality Risk Management
- **RFID:** Radio Frequency Identification
- **RPN:** Risk Priority Number
- **SCRM:** Supply Chain Risk Management
- **SLA:** Service Level Agreement
- **SOPs:** Standard Operating Procedures
- **SWOT:** Strengths, Weaknesses, Opportunities, and Threats
- **TEUs:** Twenty-foot Equivalent Units
- **TQM:** Total Quality Management
- **TTSPPs:** Time- and Temperature-Sensitive Pharmaceutical Products
- **WHO:** World Health Organizati

GENERAL INTRODUCTION

1. General Context

The pharmaceutical supply chain represents one of the most sensitive and complex logistical networks in the world. Its primary objective is to ensure the delivery of safe and effective medicines to patients, which requires close coordination among manufacturers, distributors, and regulatory authorities. This network is governed by rigorous quality standards, such as Good Distribution Practices (GDP) established by the World Health Organization (World Health Organization, 2010) , to protect product integrity. Within this framework, the pharmaceutical "cold chain" is particularly critical. Time- and Temperature-Sensitive Pharmaceutical Products (TTSPPs), such as vaccines and biologics, require strict environmental control typically between 2°C and 8°C throughout their entire lifecycle (Bishara, 2006).

Despite these strict regulations, temperature-controlled logistics remain highly exposed to operational risks. As identified by(Jaberidoost et al., 2013), pharmaceutical supply chains face a multitude of internal and external risks that can disrupt product quantity and quality. Transport vulnerabilities, mechanical breakdowns, and human handling errors frequently compromise the cold chain, leading to product degradation and severe threats to patient safety (Allen & McKenna, 2017; Zribi et al., 2019) . Furthermore, the application of Quality Risk Management (QRM) in pharmaceutical distribution remains significantly less developed compared to the manufacturing sector, leaving many supply chains operating reactively (Kumar & Jha, 2018) .

In the Algerian context, these challenges are amplified by infrastructural constraints, reliance on long-distance road transport, and the complex dynamics of public health distribution. Managing these risks is essential to guarantee pharmaceutical self-sufficiency and secure the availability of critical medicines for the population. It is within this precise context that this study examines the Central Pharmacy of Hospitals (PCH) specifically its Annaba Annex which serves as a vital artery in the national healthcare system, distributing pharmaceutical products to hundreds of public health establishments across the eastern region.

2. Problem Statement

In the Algerian public health sector, rigorous risk management within the pharmaceutical supply chain is a crucial operational requirement. Ensuring continuous access to temperature-sensitive medicines extends beyond the reactive maintenance of refrigeration units; it requires a systemic analysis of infrastructural weaknesses, particularly as the transport and final delivery stages represent the most critical points of failure (Ahmed et al., 2025). The PCH Annaba Annex faces significant daily challenges, including infrastructural limitations, high volumes of incoming stock, and long-distance transport dependencies from central suppliers in Algiers.

Although the Annex possesses functional cold rooms and internal monitoring equipment, its current risk governance lacks maturity. Management practices remain heavily reliant on the informal, experiential knowledge of the staff rather than structured, proactive Standard Operating Procedures (SOPs). The multiplicity of risks ranging from upstream transport "blind spots" to internal spatial congestion makes it exceedingly difficult to maintain absolute thermal traceability. This operational reality leads to a critical dilemma: How can regional distribution hubs accurately measure their logistical vulnerabilities, and what practical strategies can be adopted to build a resilient cold chain within the rigid constraints of the public sector?

Consequently, the central research question of this thesis is formulated as follows:

- **How can a public pharmaceutical distribution facility, such as the PCH Annaba Annex, structure an effective risk management system to guarantee the integrity, traceability, and compliance of the cold chain?**

To answer this central question, we will explore the following sub-questions:

1. **What are the specific internal and external vulnerabilities threatening the preservation of thermosensitive medicines at the PCH Annaba Annex?**

2. **How can the criticality of these logistical vulnerabilities be rigorously measured and prioritized within a highly constrained public sector environment?**

3. **What concrete Corrective and Preventive Actions (CAPA) can be implemented to transition the facility from reactive crisis management to proactive Quality Risk Management?**

3. Justification of the Choice of Subject

The choice to study risk management within the pharmaceutical cold chain is based on several strategic and operational considerations. First, mastering logistical risks is no longer a mere administrative task; it is an absolute necessity to prevent unrecognized disease vulnerability and ensure patient safety (American Society of Health-System Pharmacists, 2024). A rigorous approach to risk optimizes operational costs, prevents the destruction of expensive biological products, and ensures compliance with strict national and international regulations.

In the specific context of the PCH Annaba Annex, this topic is highly critical. As a regional hub supplying 352 healthcare establishments, any rupture in its cold chain has direct and immediate consequences for the region's public health capacity. The necessity for the PCH to reinforce its logistical resilience while operating under structural constraints fully justifies the focus of this research. Finally, from an academic perspective, this study bridges the gap between global Supply Chain Risk Management (SCRM) theories such as those defined by Ho et al. (2015) and their practical implementation in a constrained, real-world public distribution setting.

4. Research Objectives

This research aims to analyze and improve the risk management mechanisms within the pharmaceutical cold chain, using the PCH Annaba Annex as a concrete case study. The primary objective is to move beyond theoretical compliance to identify the actual, daily vulnerabilities faced by the logistical staff, evaluate the current monitoring systems, and propose highly contextualized improvements.

More specifically, the objectives are:

- To diagnose the root causes of cold chain disruptions, encompassing infrastructure, human factors, and transport operations.

- To quantitatively evaluate and prioritize these risks using structured tools such as the Ishikawa diagram, Risk Matrix, and Failure Mode, Effects, and Criticality Analysis (FMEA).
- To formulate a pragmatic Corrective and Preventive Action (CAPA) plan designed to eliminate operational blind spots and standardize internal handling procedures.
- To enrich academic reflection on proactive Quality Risk Management (QRM) by providing empirical evidence of how public-sector infrastructural limits override theoretical compliance models.

5. Academic and Managerial Relevance of the Study

5.1. Academic Relevance

This research contributes to the literature on risk management in pharmaceutical supply chains, particularly in the field of cold chain management. It provides insights into the specific challenges faced by public pharmaceutical distribution organizations in Algeria, a context that remains relatively underexplored in academic research. By combining qualitative analysis of operational vulnerabilities with structured risk assessment tools, this study enriches existing knowledge on the practical application of risk management within the pharmaceutical sector.

5.2. Managerial Relevance

From a managerial perspective, this study provides a detailed diagnosis of the vulnerabilities affecting the cold chain at the PCH Annaba Annex. The findings support decision-makers in identifying appropriate corrective and preventive actions adapted to the facility’s operational constraints. The proposed recommendations aim to strengthen thermal traceability, improve logistical procedures, and promote a more proactive approach to risk management in order to ensure the quality of thermosensitive medicines and enhance patient safety.

6. Research Methodology

To achieve these objectives, this study adopted a qualitative case-study methodology rooted in an interpretative paradigm. This approach allows for an in-depth understanding of the complex, human-driven realities of the warehouse floor. Primary data was collected through semi-structured interviews with key logistical actors at the PCH (from the Head of Operations to storekeepers and transport drivers), alongside direct field observations and internal document analysis. The qualitative data was processed using NVivo thematic coding, which directly informed the quantitative risk evaluation tools (FMEA) to ensure our strategic recommendations were grounded in empirical reality.

7. Structure of the Thesis

To address the research problem, this thesis is structured into three main chapters:

- **Chapter I** provides a detailed literature review and conceptual framework, detailing the specific requirements of the pharmaceutical cold chain and the theoretical models of Quality Risk Management (QRM).

- **Chapter II** details the organizational context and methodological framework, presenting the PCH Annaba Annex, the data collection strategy, and the analytical tools utilized (Ishikawa, Matrix, FMEA).

- **Chapter III** exposes the empirical results of the field study. It systematically identifies and scores the facility's risks before engaging in a critical discussion to propose a structured CAPA plan and strategic recommendations for sustainable improvement.

Chapter I: Literature Review And The Conceptual Framework

This first chapter reviews the literature on cold chain risk management in pharmaceutical distribution. The first section explores previous studies organized around three main themes. First, our study investigates cold chain risks, which extend beyond basic temperature changes to include both logistical breakdowns and last-mile vulnerabilities. Next, we examine how organizations handle these risks through systems of quality tools and procedures that work together as one complete process. Finally, we discuss how this proactive management system provides direct advantages that enhance supply chain effectiveness, patient protection, and regulatory compliance.

The second part of the chapter introduces the conceptual framework of our research. The goal here is to establish a clear understanding of how pharmaceutical companies protect their most sensitive products. The process begins with an examination of the fundamental regulations governing the storage and transportation of Time- and Temperature-Sensitive Pharmaceutical Products (TTSPPs). The section then presents essential risk management elements through established frameworks such as ISO 31000, Quality Risk Management (QRM), and Supply Chain Risk Management (SCRM). To conclude, this section describes our assessment tools through their theoretical background including SWOT, Ishikawa, Pareto, and FMEA while demonstrating how IoT, Blockchain, and Machine Learning technology enable organizations to foresee and prevent operational disruptions from occurring.

Section 01: Literature Review

Ensuring the quality of medicines that require controlled-temperature storage conditions is of the utmost importance during distribution, and it has been emphasized by global regulatory requirements for the handling, storage, and distribution of thermally labile pharmaceutical items (Bishara, 2006).

The documents consulted for this literature review were mainly obtained from specialized academic platforms such as Google Scholar and online university digital libraries, which made it possible to identify the main theoretical and empirical contributions related to pharmaceutical cold chain risks and their management.

This literature review is organized into three axes: the first concerns the risks associated with the cold chain in pharmaceutical distribution; the second addresses the management of these risks through methods, tools, and procedures; the third examines the contribution of this management to improving performance, safety, and compliance in pharmaceutical distribution.

1. The risks associated with the cold chain in drug distribution

The risks associated with the pharmaceutical cold chain extend beyond simple temperature fluctuations and product deterioration. In a systematic review, (Jaberidoost et al., 2013) identified 50 significant risks within the pharmaceutical supply chain, which they classified into seven main categories: supply-related risks, financial risks, logistical risks, political risks, market risks, organizational risks, and regulatory and strategic risks.

Maintaining appropriate environmental conditions, particularly temperature and humidity, is widely recognized as a critical factor in ensuring the quality and safety of temperature-sensitive pharmaceutical products during storage, handling, and transportation. In this context, strict temperature control represents a fundamental requirement of the pharmaceutical cold chain. According to (Kumar & Jha, 2018), temperature deviations must be carefully monitored, recorded, and reported to manufacturers to enable proper investigation and risk assessment within the quality management system, thereby ensuring product safety throughout its lifecycle.

Typically, heat-sensitive pharmaceutical products must be stored within a temperature range of 2°C to 8°C. Exposure to temperatures above 8°C can accelerate the degradation of active pharmaceutical ingredients, increase impurity levels, and ultimately reduce drug efficacy while potentially causing adverse effects (Bishara, 2006). Conversely, exposure to temperatures below 2°C may result in freezing, which is particularly harmful for biological products such as vaccines. A study showed that a significant percentage of vaccine shipments and storage units are exposed to temperatures below the recommended levels during storage and transportation. Exposure to freezing temperatures accelerates the loss of vaccine efficacy and also affects its quality. Vaccines, classified as biological entities, necessitate storage and transport within a defined temperature spectrum to preserve their efficacy; deviations from this range can compromise certain vaccines by modifying adjuvants and diminishing their immunological capabilities (Hanson et al., 2017).

Similarly, (Aleidi et al., 2025) demonstrated that refrigerated pharmaceutical products are frequently exposed to temperature variations throughout the distribution process due to transportation delays, power outages, and operational errors. Their analysis of FDA approved drugs revealed significant variability in thermal stability profiles, indicating that standardized decision-making following cold chain breaches remains challenging. These findings confirm that temperature excursions represent a persistent and critical risk, with potential clinical and economic consequences.

In addition to thermal risks, several studies have emphasized the importance of logistical and operational factors in cold chain integrity. (Khan et al., 2022) identified 40 risks associated with cold chain operations, highlighting product contamination, temperature and humidity fluctuations, and quality-related issues as the most critical threats. Furthermore, transportation has been identified as one of the most vulnerable stages in the cold chain. (Allen & McKenna, 2017) noted that maintaining required storage conditions throughout distribution is essential to ensure product efficacy and patient safety. However, increasing globalization and decentralization of pharmaceutical supply chains have made cold chain logistics more susceptible to disruptions related to transportation modes, route planning, third-party logistics providers, equipment reliability, shipment tracking, and regulatory compliance.

Recent studies have also highlighted the vulnerability of the final delivery stage. (Ahmed et al., 2025) reported that approximately one in every 32 shipments experiences at least one temperature deviation, with last-mile delivery identified as the most critical point of failure. This is mainly due to delays, inadequate cooling systems, improper handling practices, and insufficient infrastructure, including limited cold storage capacity, unreliable electricity supply, and lack of trained personnel. These challenges significantly increase the likelihood of cold chain disruptions and emphasize the need for improved monitoring and risk management strategies.

Consistent with these findings, (Duzgun & Kizilirmak, 2021) reported that temperature sensitive products such as insulin and vaccines are highly vulnerable during transportation and distribution. Factors such as product loss, quality degradation, delivery delays, packaging issues, and insufficient infrastructure contribute to cold chain failures. Moreover, the absence or improper use of refrigerated vehicles and temperature-controlled containers further compromises product safety.

A study conducted by Wen in 2019 highlighted the gaps in the cold chain during storage and transportation. Storage problems include inadequate planning for storage maintenance, failure of temperature and humidity control systems, and poor management of product shelf life during storage. While delivery planning issues, equipment failures, traffic or environmental disruptions, and inadequate temperature control resulting from old equipment or human errors are the main risks in the cold chain that affect transportation activities (Wen et al., 2019).

In addition, physical stress during transportation can negatively affect packaging performance. (Tang, 2015) demonstrated that vibrations, shocks, and pressure applied to insulated containers can reduce their thermal efficiency, thereby compromising their ability to maintain the required temperature range for sensitive pharmaceutical products.

Experimental studies further support these observations. (Mitrevska et al., 2025) evaluated the stability of cefixime granules for oral suspension under simulated transport conditions involving thermal cycling between -20°C and +30°C. Although the product maintained acceptable physical, chemical, and microbiological properties, several risks were identified, including exposure to extreme temperatures and delays during customs clearance.

Real-world incidents also illustrate the consequences of cold chain failures. (García, 2020) analyzed two cases of temperature excursions in a pharmaceutical distribution company and found that such deviations can significantly disrupt operations, sometimes leading to product rejection and financial losses.

Finally, evidence from hospital settings confirms the critical impact of cold chain failures on pharmaceutical management. (Zribi et al., 2019) reported that a power outage resulted in the loss of approximately 20% of temperature-sensitive drug stocks in a hospital pharmacy. Their analysis identified several contributing factors, including the absence of temperature alarm systems, lack of preventive maintenance, inadequate monitoring, and insufficient staff training. Additionally, operational weaknesses such as the use of domestic refrigerators, poor transport conditions, and limited awareness of cold chain requirements were observed. These findings highlight the vulnerability of pharmaceutical cold chains to technical, organizational, and human-related risks, emphasizing the urgent need for improved monitoring systems and staff training.

2. Risk management related to the cold chain in pharmaceutical distribution

Effective risk management in pharmaceutical cold chain distribution has become a critical requirement due to the increasing complexity and vulnerability of supply chains. (Mateo & Anich, 2018) emphasized that supply chains in the pharmaceutical industry, especially in the distribution sector, need to be redesigned. This is because traditional design does not consider the concept of risk, methods for evaluating it, or the relationship between risk, vulnerability, and resilience within the supply chain.

It relies heavily on structured quality systems and internationally recognized regulatory frameworks. According to (Haleem et al., 2015), pharmaceutical quality management is guided by major institutions such as the World Health Organization (WHO), the U.S. Food and Drug Administration (FDA), the European Union (EU), and the International Council for Harmonization (ICH). In addition to these frameworks, several operational approaches are widely implemented, including Quality Risk Management (QRM), Quality by Design (QBD), Corrective and Preventive Actions (CAPA), Six Sigma, lean manufacturing, Total Quality Management (TQM), ISO standards, and the Hazard Analysis and Critical Control Points (HACCP) system. These approaches demonstrate that risk management extends beyond risk identification and involves the implementation of integrated quality practices aimed at improving control, performance, and product safety throughout the lifecycle.

Among these tools, the Hazard Analysis and Critical Control Points (HACCP) system is considered a fundamental approach for managing risks in cold chain logistics. It enables the systematic identification, evaluation, and control of potential hazards at different stages of the supply chain, thereby ensuring product quality, safety, and operational reliability (Zhang & Chen, 2011).

Despite these advancements, (Kumar & Jha, 2018) highlighted that the application of quality risk management in pharmaceutical distribution remains less developed compared to manufacturing. To address this gap, the authors proposed a distribution-oriented risk management model based on the ICH Q9 guideline. This model incorporates key tools such as risk identification, Failure Mode and Effects Analysis (FMEA), Risk Priority Number (RPN), and CAPA to assess, prioritize, and mitigate risks across the supply chain.

Furthermore, effective cold chain risk management requires the implementation of structured and proactive practices that go beyond simple temperature monitoring. In a study conducted by (Muchabaiwa et al., 2025) , they proposed a guide for data governance and corrective and preventive management procedures designed to enhance the FEFO principle and emergency response through four integrated layers: governance, emergency management, monitoring key performance indicators, and training. Their framework focuses on standardizing deviation documentation, root cause analysis, corrective and preventive actions, and using predictive dashboards to support real-time decision-making. The study also highlights the importance of clearly defining stakeholder responsibilities, updating standard operating procedures, and using digital tools such as artificial intelligence and blockchain technology to improve product tracking, accountability, and proactive compliance in the pharmaceutical cold chain.

Similarly, integrating temperature management into a comprehensive Quality Management System (QMS) is essential. Such systems include risk assessment, documentation, and corrective actions applied throughout the product lifecycle, ensuring continuous control and improvement of cold chain processes (Kumar & Jha, 2018).

A continuous improvement approach also plays a crucial role in managing cold chain risks. (Saint-Laurent et al., 2014) described a practical implementation in a hospital setting, where a complete mapping of the pharmaceutical cold chain was conducted to identify non-compliance points. Based on this analysis, corrective and preventive measures were implemented at each stage, including the development of formal procedures, optimization of temperature control at reception, enhancement of cold storage capacity, improved tracking during distribution, and qualification of transport equipment. To ensure sustainability, regular audits and monitoring systems were established, demonstrating the importance of feedback loops in maintaining cold chain integrity.

In recent years, digital technologies have significantly strengthened risk management practices in pharmaceutical distribution. (Zhang et al., 2021) demonstrated that integrating blockchain technology, cloud computing, and the Internet of Things (IoT) can improve cold chain monitoring and traceability. Their system assigns unique identifiers to pharmaceutical products, records real-time environmental and operational data, and secures these data through blockchain verification, thereby reducing the risk of data manipulation and improving coordination among stakeholders.

Similarly, (Wang,2024) highlighted the growing reliance on advanced monitoring technologies such as real-time temperature sensors, automatic alarm systems, RFID, wireless sensor networks, and cloud-based platforms. These tools enable early detection of temperature deviations and support rapid corrective actions. In addition, compliance with Good Distribution Practices (GDP) and inventory management principles such as First Expired, First Out (FEFO) are essential components of effective cold chain risk management.

3. The contribution of risk management to the improvement of performance, safety, and compliance

Machine learning methods are increasingly used in pharmaceutical cold chain logistics to improve operational efficiency and safety. (Chowdhury, 2025) demonstrated that integrating machine learning models such as Random Forest and LSTM with IoT-based monitoring systems can significantly improve temperature control and aid in regulatory compliance in cold chain distribution. This is further highlighted by a case study on the pharmaceutical distributor Medi Cool, where the implementation of machine learning algorithms resulted in a 25% reduction in temperature deviations, a 20% decrease in operational costs, and more than 98% compliance with FDA standards over a one-year period. Ultimately, these findings illustrate the potential of data-driven approaches to optimize cold chain performance and reduce operational risks.

In parallel, (Trendova Trendov , 2024) research indicates that the adoption of energy efficient cooling systems, the utilization of renewable energy, and the incorporation of real-time monitoring technologies synergistically mitigate operational risks while bolstering the dependability of cold chain logistics. Furthermore, the integration of risk management strategies with sustainable technologies empowers organizations to fortify the resilience of cold chain systems, thus safeguarding the integrity of temperature sensitive pharmaceutical products. Digital instruments, such as Internet of Things (IoT) sensors, blockchain systems, and data analytics, facilitate product tracking, temperature monitoring, and prompt responses to anomalies, thereby minimizing product damage and ensuring adherence to regulatory mandates.

Furthermore, machine learning techniques can analyze both historical and real-time data to predict temperature fluctuations, identify patterns, and detect anomalies before they compromise product quality. (Martinez, 2025) highlighted that these predictive capabilities enable proactive decision-making and timely corrective actions, ultimately reducing product losses and ensuring compliance with regulatory requirements.

4. Positioning of the present study

The present study is positioned at the intersection of pharmaceutical supply chain risk management and cold chain distribution performance. It is grounded in the observation that, although the existing literature provides substantial insights into supply chain risks, digital traceability tools, and regulatory compliance mechanisms, there remains a need for research that effectively connects these frameworks to real-world operational contexts.

In particular, contextual challenges associated with limited resources, infrastructural weaknesses, and uneven regulatory environments remain insufficiently addressed. These constraints can significantly influence the effectiveness of cold chain practices and increase the vulnerability of pharmaceutical distribution systems.

Accordingly, this study adopts a contextualized perspective and positions itself as an attempt to bridge the gap between global supply chain risk management (SCRM) approaches and their practical implementation in comparable pharmaceutical distribution settings.

By doing so, it aims to contribute both theoretically, through a more context-sensitive understanding of risk management, and practically, by providing insights that may support resilience, safety, regulatory compliance, and overall performance improvement in cold chain systems.

Section 02: Conceptual Framework

This conceptual framework aims to establish a complete understanding of how pharmaceutical companies protect their most critical assets. Organizations need to combine their actual distribution network operations with existing risk management methods to achieve effective control of risks in temperature-controlled logistics.

The framework consists of three main areas that investigate the link between its components. It begins by examining the fundamental elements that create pharmaceutical cold chain systems, which require special storage and transport methods to protect Time- and Temperature-Sensitive Pharmaceutical Products. It also establishes risk management principles through the examination of Quality Risk Management (QRM) and ISO 31000 as structured frameworks for handling uncertainty.

The framework demonstrates how organizations use operational knowledge to assess existing threats affecting cold chain operations, including physical, environmental, and operational risk factors. It further shows how modern supply chains use advanced digital technologies such as IoT sensors, Blockchain, and Machine Learning to predict and prevent logistical failures before they occur.

1. The Pharmaceutical Cold Chain Distribution: Conceptual Foundations and Specific Requirements

This section investigates the basic principles that define pharmaceutical cold chain distribution operations. Tracing the development of temperature-controlled logistics from its origins to its present state, it establishes the fundamental definitions of the cold chain network. Furthermore, the text specifies the storage and transportation methods required to handle Time- and Temperature-Sensitive Pharmaceutical Products (TTSPPs). Finally, it demonstrates how continuous cold chain maintenance protects product effectiveness and patient safety while helping organizations comply with Good Distribution Practices (GDP) requirements.

1.1. Origins and Historical Evolution of the Cold Chain

In the 18th century, fishermen utilized ice and salt to preserve fish while at sea, coinciding with the initial development of refrigerated transportation and the storage of temperature-sensitive commodities. The expansion of the ice trade during the 19th century, originating in New England and extending to the Caribbean, Latin America, and Asia, facilitated the advent of refrigerated transportation. Wood chips were used as insulation (Ren, 2024). Subsequently, the 20th century witnessed the widespread adoption of refrigerated ships and cargo, a consequence of advancements in refrigeration systems.Tropical fruits from Central America started to reach North America, frozen meat from Australia and New Zealand started to reach the UK, and frozen meat from South America started to reach France.

Globalization in the late twentieth century fueled the development of refrigerated cold chain containers, or "reefers": in 2018, approximately 2.9 billion twenty-foot equivalent units (TEUs) of reefers were used, accounting for approximately 5% of global ISO container capacity (Ren, 2024).Modern cold chain networks are now a standard and essential component of globalized trade, providing the foundational logistics infrastructure needed for highly temperature-sensitive industries such as pharmaceutical distribution.

1.1.1. Definition of the Cold Chain

The cold chain is a temperature-controlled supply chain and a specialized system of transporting and storing temperature-sensitive products, especially pharmaceuticals, vaccines, blood components, and other medical products, from procurement to fulfilment, within a specific safe temperature range during storage and distribution in order to preserve their quality, safety, and efficacy (Iyer & Robb, 2025; Ministry of Public Health Lebanon, 2024; Nyirimanzi et al., 2023; Pan & Zuo, 2024).

1.1.2. Definition of Pharmaceutical Distribution

Pharmaceutical distribution is the procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of pharmaceutical products, with the exception of the dispensing or providing pharmaceutical products directly to a patient or his or her agent. In the pharmaceutical supply chain, distribution is a key operation. It is the storage and flow of pharmaceuticals after being dispatched by the final production points or suppliers until it reaches the clients or end users. The primary goal of pharmaceutical distribution is to ensure a consistent supply of quality-assured pharmaceuticals to service delivery points in a cost-effective manner (Getahun et al., 2025; WHO, 2010).

1.1.3. Main requirements and Components of Pharmaceutical Cold Chain Distribution

Pharmaceutical cold chain distribution involves a broad spectrum of activities, including procurement, purchase, storage, shipping, repackaging, relabeling, and stringent documentation and record-keeping (WHO, 2010). The primary necessity of these measures is to retain the pharmaceutical product's quality and identity across the whole distribution network. Operationally, this specialized logistics system relies largely on controlled warehousing and transit infrastructure to ensure drugs maintain optimum humidity and temperature conditions from manufacture through to final sales (Ren, 2024).

Consequently, the major physical and organizational components necessary to sustain this system include certified cold storage facilities, refrigerated transport vehicles, continuous environmental monitoring equipment, redundant backup systems, and highly trained staff (Ren, 2024; WHO, 2011).

1.2. Temperature-Sensitive Pharmaceutical Products and Their Distribution Requirements

Good Distribution and Storage Practices specify that temperature-sensitive products are to be stored, handled, and distributed carefully throughout the distribution network to maintain product quality, safety, and efficacy. Temperature is one of the most important parameters to control, and pharmaceutical storage and transit conditions must align with predetermined conditions as supported by stability data. Temperature excursions outside of respective labeled storage conditions, for brief periods, may be acceptable provided stability data and scientific technical justification exists demonstrating that product quality is not affected. Additionally, the warehouse should provide suitable fire detection and fire-fighting equipment and receiving bays designed to avoid conflict between incoming and outgoing goods while protecting products from direct sunlight, dust, dirt, rain, snow, wind, and extremes of heat, cold, and solar radiation (MOPH Lebanon, 2024).

1.2.1. TTSPPs

“Any pharmaceutical good or product which, when not stored or transported within predefined environmental conditions and/or within predefined time limits, is degraded to the extent that it no longer performs as originally intended” (WHO, 2011).

Table I: Cold chain product classification and preservation temperature ranges

Product types	Examples	Aim of the cold chain	Preservation temperature ranges
Pharmaceuticals	Vaccines, biologics, blood	Maintain potency, efficacy and safety	2 to 8 °C, below -20 °C
Fresh produce & seafood	Fruits & vegetables & seafood	Prevent spoilage and maintain freshness	-5 °C to 5 °C
Refrigerated/Frozen food products	Refrigerated/Frozen meat, vegetables, diary & seafood	Prevent bacterial growth and maintain quality	-5 °C to 5 °C, Below -18 °C
Chemicals	Liquid nitrogen/oxygen/ carbon dioxide, liquefied natural gas	Prevent explosion and maintain quality	Below -160 °C

Source: Modified from (Ren., 2024)

1.2.2. Storage Requirements in Pharmaceutical Cold Chain Distribution

Medicines requiring controlled-temperature storage conditions must be distributed in a manner that ensures their quality will not be adversely affected (Bishara, 2006). The primary requirements include:

- **Qualification and Mapping:** Every new temperature-controlled store must be qualified before it is released for the routine storage of TTSPPs through a fully documented verification process. This temperature mapping procedure must demonstrate the air temperature profile throughout the storage area, when empty and in a normal loaded condition, while identifying zones which should not be used for storage (such as areas in close proximity to cooling coils, cold air streams, or heat sources). Mapping must also demonstrate the time taken for temperatures to exceed designated limits in the event of power failure (WHO, 2014, 2015a).

- **Capacity and Infrastructure:** Ensure that the net storage capacity of the temperature-controlled stores is sufficient to accommodate peak TTSPP stock levels and associated transit temperature protection components to avoid the risks associated with overstocking and to ensure that good warehousing practices can be adopted, specifically first in-first out (FIFO) or earliest expiry-first out (EEFO). Storage facilities should be specifically designed to hold TTSPPs. These facilities must include an auto-defrost function, a low-temperature protection system, and a calibrated, continuous temperature monitoring system. This system should have sensors placed in areas where temperature changes are most pronounced and where temperature extremes are likely to occur (WHO, 2011).

- **Quarantine and Traceability:** The warehouse needs a designated quarantine space. This area is for isolating returned, defective, recalled, or otherwise withdrawn items until a decision is made about their disposition – whether they will undergo disposal or re-stocking. If a temperature monitoring alarm is triggered, the products in question must be physically separated within this quarantine zone. This is until a thorough investigation is completed, using manufacturer stability data to decide the next course of action. Records must be kept to prove compliance and to show an unbroken chain of custody (MOPH Lebanon, 2024; WHO, 2011, 2015e).

- **System Maintenance:** Regular preventive maintenance must be carried out on all temperature-controlling equipment to eliminate leakage of refrigerant into the environment. Maintaining cold stores and insulated envelopes is essential to achieving their intended lifespan, and everyone working on these systems needs appropriate training (WHO, 2015c).

1.2.3. Transport Requirements in Pharmaceutical Cold Chain Distribution

Transportation is a highly vulnerable link in the cold chain, demanding strict operational oversight to ensure temperature stability. Staff responsible for transport operations need to understand the importance of temperature stability for pharmaceutical products and the basic concepts of packaging thermodynamics and good documentation practice (WHO, 2015d). The fundamental requirements include:

- **Agreements and Vehicles:** Any carrier contracted to transport TTSPPs by air or by sea must operate under the terms of a formal service level agreement (SLA) responsible for maintaining load temperatures within the defined transport temperature profile. Temperature-controlled road vehicles must be capable of maintaining the temperature range defined by system set points over the full annual ambient temperature range experienced over known distribution routes. Vehicles must be equipped with calibrated temperature monitoring devices, alarms to alert the driver in the event of excursions, and doors with security seals or locks (WHO, 2011).

- **Packaging Architecture:** Thermal protection requires the selection of either active refrigerated systems or passive packaging architectures, such as insulated containers using phase change materials, flexible ice blankets, or dry ice. Shipping containers must be packed to the exact specified configuration to minimize the risk of mechanical damage and protect freeze-sensitive products against temperatures below **0 °C** when frozen packs are used (Ren, 2024; WHO, 2011).

- **Labeling and Delivery:** Containers must be clearly labeled to identify the correct transport temperature range and orientation for handling. TTSPPs should be sent to outside recipients using the best available transportation methods to minimize transit times. Before using the product, it's also important to give patients clear instructions on how to store it properly (WHO, 2011).

1.3. Objectives and Importance of the Pharmaceutical Cold Chain

The importance of the pharmaceutical cold chain is tied to its role in maintaining drug safety, quality, and efficacy across the entire distribution network (Ministry of Public Health Lebanon, 2024). Adherence to cold chain protocols is required because failures represent a triple risk for hospital establishments, encompassing financial, regulatory, and patient safety concerns. Consequently, the central objectives of this logistical framework are to ensure product integrity through environmental controls, support patient safety by preventing unrecognized disease vulnerability, achieve regulatory compliance through Good Distribution Practices (GDP), and mitigate the financial impact of medication loss and costly revaccination (ASHP, 2024).

1.3.1. Ensuring Product Quality, Safety, and Efficacy

Cold chain management for temperature-sensitive pharmaceuticals focuses on ensuring that the quality and efficacy of the product will not be compromised. Good Distribution and Storage Practices specify that products are to be stored, handled, and distributed carefully throughout the distribution network to maintain safety. Environmental controls play a key role, where temperature remains one of the most important parameters to control. Therefore, drugs must be stored and transported according to predetermined conditions supported by stability data (MOPH Lebanon, 2024). This necessity is amplified by the rapid introduction of medicines requiring precise temperature control, including biologics, compounded infusions, and specialty drugs, which expands requirements for unique handling and storage needs. Preventing temperature excursions throughout handoffs is critical to maintaining product integrity (ASHP, 2024).

1.3.2. Supporting Patient Safety and Continuity of Supply

Cold chain management errors lead to patient harm and unknown disease vulnerability. Errors with vaccine use result in unintended and unrecognized vulnerability, leaving patients unprotected against severe disease and potentially requiring costly revaccination. Health-system pharmacies meet significant management challenges, including the need to ensure consistent monitoring of product storage temperatures across the organization. The risk of temperature excursions leads directly to the loss of medications and a negative impact on patient care (ASHP, 2024).

1.3.3. Ensuring Regulatory Compliance and Distribution Performance

To maintain the original quality of pharmaceutical products, every party active in the distribution chain has to comply with applicable legislation and regulations. Every activity should be carried out according to the principles of GMP, Good Storage Practice (GSP), and Good Distribution Practice (GDP) (WHO, 2010).

- **The Function of GDP:** Good Distribution Practices (GDP) represent the part of quality assurance that ensures medical product quality is maintained by means of adequate control of the activities occurring during the trade and distribution process. This serves as a tool to secure the distribution system from falsified, unapproved, illegally imported, stolen, substandard, adulterated, or misbranded medical products (WHO, 2020).

- **Documentary Evidence:** For quality assurance purposes, stakeholders in the supply chain should be able to supply documentary evidence that the pharmaceutical product has not exceeded acceptable limits of time, temperature, and humidity exposure, as determined by the manufacturer’s stability data (WHO, 2011).

- **Recording technology**: Devices and technology that record temperature or humidity during transportation and external dissemination give the exposure history (WHO, 2011).

2. Risk and risk management

This section is dedicated to the fundamental principles of risk and its management. The core concept of risk together with its governing principles of risk management and the operational process will be explained through this assessment. The primary objective of this study is to develop a strong theoretical framework which enables organizations to comprehend the significance and functions of risk management.

2.1. Fundamental Definitions

This subsection establishes standardized vocabulary for core concepts which will enable precise academic comprehension of the material while maintaining international standardization.

2.1.1. Core Concepts: Risk, Hazard, Probability, Severity, Uncertainty and Risk management

A **hazard** is primarily defined as "the potential source of harm" (ICH, 2023). Its assessment process evaluates its impact through **severity** (gravity), which serves as "a measure of the possible consequences of a hazard by evaluating the magnitude of the consequences of an event and translating the potential impact on people, the environment, or assets in the case of a danger occurring" (ICH, 2023; Rausand, 2011). The definition of **risk** requires two essential elements which include "the combination of the probability of occurrence of harm and the severity of that harm" (ICH, 2023). Within organizational frameworks, risk is defined as "the effect of uncertainty on objectives" (ISO, 2018), or as "an uncertain event or condition that, if it occurs, has a positive or negative effect on one or more project objectives" (PMI, 2021). From a broader academic perspective, Wang and Jie (2020) describe risk as the potential for loss, injury, or unfavorable circumstances. Specifically, they note it represents a quantifiable factor such as the threat of financial damage or failure used to evaluate the potential profitability of an investment or commercial enterprise.

Probability serves as a measurement tool that defines event occurrence based on the ratio of actual events divided by the total number of events, which researchers often show as a percentage or frequency value throughout designated time periods (Hopkin, 2018). These measurable factors are distinguished from **uncertainty**, which refers to "a lack of knowledge about hazards, harms, and their associated risks," or "a lack of understanding and awareness of issues, events, paths to follow, or solutions to pursue" (ICH, 2023; PMI, 2021). Uncertainty is further described as "the quality of being indeterminate as to magnitude or value and indeterminate in respect of duration or occurrence; in economics, it represents a business risk which cannot be measured and whose outcome cannot be predicted or insured against" (Wang & Jie, 2020).

Risk management at the institutional level includes "coordinated activities to direct and control an organization regarding risk" which requires "the systematic application of quality management policies, procedures, and practices to the tasks of assessing, controlling, communicating and reviewing risk" (ISO, 2018; ICH, 2023). The term describes "the specific strategies, methods, and supporting tools deployed to identify and keep these risks at an acceptable level" (Alhawari et al., 2012).

2.1.2. Typology of Risks:

Organizational risks can be comprehensively categorized into four primary domains:

Business Risk: Business risk covers the uncertainties related to a company's market and overall management. (Lam, 2003) breaks this down into four specific factors:

- **Strategic Risk:** The risks that come from major executive decisions, dealing with competitors, and the general path the leadership decides to take.
- **Volume and Margin Risks: The** threat of sales dropping or profit margins shrinking.
- **Franchise and Reputation Risks:** Any potential threat to the brand's reputation or the customer trust established by the business.
- **Compliance Risk: The** danger of failing to keep up with industry rules, laws, and legal standards.

Financial Risk: The financial uncertainties which arise from a business's cash flow operations and its asset ownership and debt obligations (Lam, 2003).

- **Market Risk:** The impact of market changes negatively affect the business. This includes price risk (when the value of assets drops) and liquidity risk (when a company cannot easily sell off assets to get cash without taking a huge loss).
- **Credit Risk:** The chance of losing money because a client, partner, or supplier fails to pay their debts or honor a financial contract.

Operational Risk : The daily challenges which businesses face to maintain their operational activities. The term defines operational risk as the occurrence of internal system failures which include human error and process breakdowns and system breakdowns and technology disturbances and security violations (Lam, 2003).

Environmental Risk : The first three risk categories examine internal company operations while environmental risks originate from external environmental conditions. Companies have almost no control over these hazards . In the context of modern logistics and supply chains, these macro-level threats are heavily emphasized because they can disrupt entire networks simultaneously (Ho et al., 2015). Environmental risks encompass:

- **Natural and Ecological Disasters:** Extreme weather events, earthquakes, pandemics, or climatic shifts that physically damage infrastructure or halt transportation routes.
- **Socio-Political and Regulatory Shifts:** Sudden changes in government regulations, geopolitical instability, trade embargoes, or broader macroeconomic crises that alter the business landscape.

2.1.3. Steps for Risk Management

Risk management functions as an ongoing process which follows a methodical approach to handle potential hazards. Achieving operational resilience requires following a systematic framework which consists of five essential stages.

- **Risk Identification:** The initial phase of the process requires a complete investigation to discover all possible dangers which may interrupt supply chain operations. The goal of this process is to create a precise record of all events which have the potential to affect the organization, its business partners and its customers (Harland et al., 2003).

- **Risk Assessment:** Once threats are identified, they must be assessed. The evaluation process applies two primary criteria: the probability of occurrence and the extent of resulting financial damages, which include both direct and indirect losses (Hauser, 2003).

- **Development of Management Strategies:** This step involves creating specific procedures which companies will use to prevent problems and correct issues which arise from identified security risks. The organization will implement three specific actions which include process optimization, staff training, and establishment of strategic partnerships to share risk management responsibilities with all network participants (Hallikas et al., 2004).

- **Continuous Monitoring and Evaluation:** Organizations need to monitor their system vulnerabilities continuously. Organizations can use measurement systems to monitor how often risks happen while they measure how well their prevention methods work (Hallikas et al., 2004).

- **Treatment of Risks:** While organizations establish effective safety measures to reduce risk, some threats will inevitably remain. This final step involves accepting and analyzing these residual risks, while preparing intervention scenarios to minimize their impact (Kleindorfer & Saad, 2005).

2.2. ISO 31000

The ISO 31000 standard, initially published in 2009 and then revised in 2018, constitutes an internationally recognized framework for risk management. It offers principles and guidelines for adopting a structured, coherent, and integrated approach. This framework aims to support strategic and operational decisions by helping entities identify, analyze, evaluate, treat, monitor, and effectively communicate risks.

Unlike other ISO standards, ISO 31000 does not allow for formal certification. Its main objective is to promote continuous improvement by encouraging organizations to integrate this approach into their governance, culture, and daily processes.

In a context of uncertainty and rapid changes, ISO 31000 acts as a guide:

- **Global understanding:** shared within an organization.

- **Strategic decision-making:** integrated into the various dimensions of governance.

- **Operational excellence:** identifying threats and opportunities at the right time.
- **Proactive approach:** transforming challenges into strategic advantages.
- **Stakeholder confidence:** to demonstrate that the organization is well-prepared for uncertainties.

2.2.1. The principles of ISO 31000

The standard is based on a set of principles that constitute the foundation of effective, coherent, and sustainable risk management, in order to preserve the entity's resilience:

- **Integrated:** incorporated into all activities and at all levels of the organization.
- Structured and comprehensive approach: a coherent and comprehensive method to ensure a unified vision.
- **Adapted:** adjusted to the internal and external context of the organization and its objectives.
- **Inclusive:** involving relevant stakeholders allows for the appreciation of their expertise, concerns, and viewpoints.
- **Dynamic:** anticipates and continuously detects variations, quickly assesses their effect, and adjusts its actions.
- **Best available information:** relies on reliable and varied data, while explicitly incorporating their limitations and uncertainties.
- **Human and cultural factors:** values, behaviors, and organizational culture exert a decisive influence.
- **Continuous improvement:** constantly enriched thru feedback and organizational learning.

Source: ISO 31000.

2.3. Quality Risk Management

This subsection examines Quality Risk Management (QRM) as an industry-specific framework which protects product integrity and patient safety according to established universal risk principles.

2.3.1. Definition and Scope of QRM

Guaranteeing the integrity of medications is a vital priority over their entire lifesycle, as this ultimately defines patient safety and product acceptance . Recognizing this necessity, health authorities worldwide have built tight frameworks to help enterprises identify, mitigate, and monitor possible threats. As a result, mitigating these risks is now a basic component of industrial quality assurance (Kumar & Jha, 2018). Formally, Quality Risk Management (QRM) represents a structured technique used to analyze, mitigate, share, and re-evaluate risks threatening drug quality at each point of the product's existence, allowing management to make informed decisions at any stage (Haleem et al., 2015; ICH, 2023).

2.3.2. Primary Principles of QRM

The operational logic of the QRM framework is founded upon two basic rules. First, any evaluation of quality threats must be established in sound scientific data, with the ultimate goal of keeping the end-user (the patient) safe. Second, the resources, formal procedures, and paperwork allocated to the process must be precisely proportional to the actual severity of the detected risk (ICH, 2023; Kumar & Jha, 2018).

2.3.3. QRM in Manufacturing vs. Distribution

While risk management measures are deeply established in the daily routines of manufacturing sites, they are surprisingly often forgotten once the products enter the distribution channels. Yet, logistics networks have the significant burden of conserving the drug's qualities right up to its expiration date. Equipping supply chain operators with a firm grasp of QRM ideas is therefore crucial, as it helps them to protect the delivery of pharmaceuticals considerably more efficiently (Kumar & Jha, 2018).

2.3.4. The QRM Process Steps

The practical deployment of this system normally follows a four-phase cycle (ICH, 2023):

- **Risk Assessment:** This initial phase entails detecting potential threats and analyzing both the possibility and the effects of being exposed to them.
- **Risk Control:** Here, managers make strategic choices to either lessen the hazard to a bearable threshold or to accept it. The energy and resources engaged in this stage should closely match the danger's size.
- **Risk Communication:** This relies on an ongoing exchange of data regarding hazards and mitigation methods among all relevant stakeholders at any point of the cycle.

- **Risk Review:** Risk monitoring is not a one-time occurrence. Organizations must build procedures to regularly monitor incidents and adapt their strategy based on new discoveries or operational input.

2.4. Supply Chain Risk Management

Supply chain management operates as a complicated system which connects purchasing, manufacturing, storage, and transportation activities to support uninterrupted product movement, financial transactions, and operational data exchange between partner organizations (Christopher, 2016). Modern supply chains depend on their interconnected systems because all operational parts of the supply chain will break down when the weakest link in the system fails (Ferrahi & Bouzadi, 2016).

SCRM has developed into an important strategic method which addresses these fundamental security weaknesses. The SCRM system functions as an active system that unites different organizations through basic assessment methods which include both quantitative and qualitative information to identify potential threats, evaluate their impact, and develop solutions before these threats become real (Ho et al., 2015). Pharmaceutical cold chain logistics requires effective SCRM because it protects time- and temperature-sensitive pharmaceutical products through security measures that maintain product quality and compliance with regulatory standards.

2.4.1. Definition of SCRM

Table II: Definition of (SCRM) from different perspectives of researchers.

Authors	Definitions
(Piyush Singhal et al., 2011)	"Supply chain risk management integrates the organizations to enhance efficiency and effectiveness in delivering products and services."
(Ghadge et al., 2012)	"(SCRM) It is a structured and systematic approach to identify, assess, and mitigate supply chain risks to maintain performance and resilience."
(William Ho et al., 2015)	"It involves defining and operationalizing risks and developing strategies to mitigate them effectively."

(Gurtu Amulya & Jestin Johny, 2021)	"Supply chain risk management (SCRM) is a systematic, phased approach to recognizing, evaluating, ranking, mitigating, and monitoring potential disruptions in supply chains."
(Abdulatifu Hemed, 2025)	"Supply Chain Risk Management (SCRM) involves identifying, assessing, and mitigating risks that can disrupt the flow of goods, information, and funds within supply chains. It aims to enhance the resilience and efficiency of supply chain operations."

Source: Modified from (Sharifi & Naimzad, 2026).

2.4.2. SCRM in the Pharmaceutical Setting

In the pharmaceutical industry, the best way to start figuring out how to deal with supply chain uncertainty is to make a list of all the possible risks. This industry is closely linked to drug development and patient health, so any weaknesses in product quality are always the most important thing to look at. Real-world pharmaceutical logistics are very delicate; even a small mistake can cause huge problems with operations. Also, risks don't usually happen on their own, which makes it harder for managers to deal with them. Decision-makers need to deal with both internal and external risks at the same time to deal with this changing environment. In general, they use two main strategies: either they go after the main cause of the uncertainty to get rid of it, or they change the supply chain to deal with the shock and limit the damage without having to fix the root of the problem (Wang & Jie, 2020).

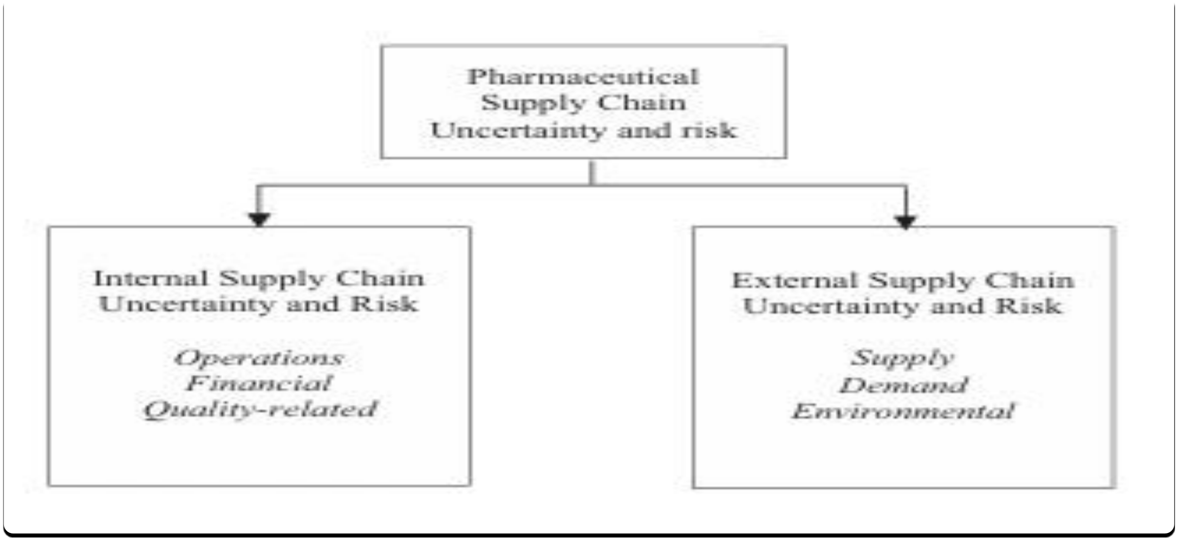
2.4.3. Risk Typology in Pharmaceutical Logistics

Researchers often put different kinds of uncertainty into groups to protect these weak networks. The most common way to look at these threats is to group them into two big categories based on where they come from (Wang & Jie, 2020):

- **External Risks (Macro-Level):** These come from the larger world and are things that the company can't directly control. Some examples are sudden changes in supply and demand, political instability, natural disasters, and larger economic trends like shorter product lifespans or faster technology growth (Ferrahi & Bouzadi, 2016; Wang & Jie, 2020).
- **Internal Risks (Micro-Level):** These are problems with the organization's day-to-day operations that happen within the organization or with its closest partners. They

include things like unstable finances, broken equipment, bad management choices, and special problems with drug formulation and quality (Wang & Jie, 2020). It is also important to note that as supply chains get more complicated and use more technology, companies often lose sight of and control over them, making it much harder to deal with these internal risks (Ferrahi & Bouzadi, 2016).

Figure 1: Types of supply chain uncertainty and risk from the pharmaceutical firms perspective.



Source: (Wang & Jie, 2020)

2.4.4. SCRM Process

To handle such a wide range of risks, a company needs a well-organized risk management plan that is always in place to make it stronger . Scholars generally agree that a strong SCRM framework goes through five stages that are all connected (Ho et al., 2015; Sharifi & Naimzad, 2026):

- **Risk Identification:** Finding possible threats in the company, its larger network, and the outside world, and then figuring out if they would cause normal delays or complete shutdowns.
- **Risk Assessment:** Carefully considering how likely a hazard is to happen and how much damage it could really do.
- **Risk Mitigation and Planning**: Making strategic action plans to deal with the risks that have been found, lessen their impact, and speed up the recovery process.

- **Risk Control and Implementation:** Making those strategic plans a reality and making sure they are a part of the company's daily operations.
- **Continuous Improvement:** Using what you learned from past problems to always improve how the company deals with future risks.

Figure 2: Supply chain risk management process

Source: (Sharifi & Naimzad, 2026)

2.5. Methods and instruments for risk identification, assessment, and monitoring

Theoretical risk management frameworks require specific tools for their transition into actual implementation. The ability of an organization to deploy organized assessment methods directly determines the performance of its protection system.

2.5.1. Context and Diagnostic Tools

An organization requires a complete understanding of its operational environment before it can study particular breakdowns.

- **SWOT Analysis:** This strategic tool allows managers to evaluate the internal Strengths and Weaknesses of their logistical infrastructure against the external

Opportunities and Threats present in the macro-environment (Helms & Nixon, 2010).

2.5.2. Identification and Root-Cause Analysis Tools

The process of understanding the environment requires organizations to identify their particular security weaknesses, which they will then trace back to their original sources.

- **Criticality Analysis:** Is an internal and external audit aimed at identifying critical points and vulnerabilities within the supply chain (Dakhch, 2024).

- **Ishikawa Diagram (Fishbone Diagram):** This analytical tool creates a systematized classification system which separates the essential root causes of logistical problems into six specific categories : Manpower, Methods, Machines, Materials, Milieu, and Measurement. By expanding the traditional model to include "Measurement" a critical addition for evaluating thermal traceability and sensor accuracy in the pharmaceutical sector this framework ensures management addresses the true structural source of the failure rather than just the visible symptoms (Ishikawa, 1985).

2.5.3. Assessment and Quantification Tools

The mathematical measurement of risks serves as the fundamental requirement for conducting effective risk prioritization.

- **FMEA:** A highly structured, proactive methodology that evaluates systems to find their precise failure points. The system calculates a Risk Priority Number (RPN) which combines three factors: Severity, Occurrence, and Likelihood of Detection (Mailena et al., 2021).

- **Pareto Analysis (The 80/20 Rule):** This enables organizations to identify their most important problems through statistical analysis, which demonstrates that 80 percent of logistical failures emerge from 20 percent of recognized causes. This method enables managers to direct their resources toward areas that will produce maximum results (Jum’a & Basheer, 2023).

2.5.4. Visualization and Prioritization Tools

Risk mapping serves as the ultimate standard for displaying risks to decision-makers through graphical interface systems.

- **The Risk Matrix:** This enables users to classify identified threats through two measurement dimensions which assess their likelihood of occurring and their potential destructive power (Hill & Cole, 2025).

- **The Heat Map:** This provides an advanced graphical representation of the matrix which uses a color spectrum to show risk levels, displaying operational zones that require urgent attention by highlighting their most sensitive areas (ISO, 2018).

2.5.5. Risk Treatment Mechanisms

The organization needs to build response plans after the AMDEC process establishes risk priorities and their identification through mapping. The process needs three different operational documents to function properly:

- **The Mitigation Plan:** This document collects all preventive measures which aim to decrease both the frequency and the severity of risk events (Nel, 2024).

- **The Contingency Plan:** Unlike mitigation which is preventive, the contingency plan is reactive. These are predetermined emergency situations which serve as backup plans, implemented during significant operational disruptions to enable quick business recovery (Pettit et al., 2008).

- **CAPA:** A structured methodology required by pharmaceutical quality systems to investigate incidents and implement permanent procedural changes to prevent recurrence (ICH, 2023).

2.5.6. Continuous Monitoring and Control Tools

Monitoring is the dynamic phase of the process. It ensures treatment strategies remain effective in an unstable environment (ISO, 2018).

- **KRI:** While KPIs measure the success of a past action, KRIs are predictive tools for early warning. They measure variables (like temperature fluctuations or delivery delays) to announce the emergence of a threat before it strikes (Boyens et al., 2022).

- **The Risk Dashboard:** It is the digital interface that aggregates data from KRIs. This tool offers decision-makers a comprehensive, real-time view of the company's risk exposure. By displaying trends of improvement or deterioration, the dashboard serves as the ultimate tool for strategic decision-making (MxD, 2023).

3. Pharmaceutical Cold Chain Risk Management

The previous chapter established the theoretical foundations of Quality Risk Management (QRM) within the pharmaceutical industry. However, theory must eventually meet practice. This chapter introduces a method to implement risk management methods inside temperature-controlled logistics which face extreme quality threats. The cold chain system requires its own unique monitoring because it depends on continuous mechanical systems and complicated human activities more than regular supply chain operations.

The chapter starts with a study of temperature-controlled network vulnerabilities which protect Time- and Temperature-Sensitive Pharmaceutical Products (TTSPPs). The chapter will show managers how to use the QRM framework for assessing and managing their daily operational dangers. The chapter shows how pharmaceutical companies use advanced technologies which include the Internet of Things (IoT), Blockchain, and Machine Learning to prevent temperature changes that could harm their products.

3.1. Vulnerabilities in Temperature-Controlled Logistics

While standard logistics networks primarily optimize cost and delivery speed, pharmaceutical cold chains impose an extra environmental requirement. The cold chain system must maintain strict operational oversight because it depends on constant temperature control through all its distribution points (Allen & McKenna, 2017). A standard supply chain system experiences only time loss when it encounters logistical delays. In contrast, the cold chain system needs active refrigeration to prevent product destruction when it encounters those same delays.

Temperature-controlled logistics systems depend on two main components that make them vulnerable to operational failure. First, the distribution of environmentally sensitive items requires highly specialized equipment, and any disruption to this infrastructure immediately compromises the safety of the medicine (Allen & McKenna, 2017). Second, the pharmaceutical cold chain requires multiple handoffs that occur between manufacturers, third-party logistics providers (3PLs), airport handlers, and hospitals. Products that transfer between controlled spaces (such as between refrigerated trucks and warehouse receiving bays) experience high exposure risks (Duzgun & Kizilirmak, 2021).

The existing operational difficulties of cold chain management, combined with a lack of trained experts who can deal with emergency situations, create severe operational challenges (Rout et al., 2024). Uncontrolled vulnerabilities result in immediate consequences when organizations fail to manage them. Whenever a logistical failure occurs, a temperature-controlled network suffers financial losses, violates strict regulations, and endangers public safety. Organizations need to understand their existing operational weaknesses because this knowledge serves as the essential base for developing risk assessment and mitigation strategies.

3.2. Typology of Cold Chain Risks

Since the pharmaceutical cold chain operates as a highly complex socio-technical system, managers must accurately categorize threats to allocate protective resources effectively. Pharmaceutical supply chains face a multitude of internal and external risks that can disrupt product quantity, quality, and delivery schedules (Jaberidoost et al., 2013). In the specific context of temperature-controlled networks, researchers generally group these vulnerabilities into three primary domains based on their origin: physical infrastructure failures, operational and human errors, and external environmental variables (Duzgun & Kizilirmak, 2021; Ren, 2024).

- **Physical and Infrastructure Risks:** The most significant danger to product protection occurs when refrigerated trucks, active shipping containers, and warehouse storage units experience mechanical breakdowns, because these failures lead to immediate temperature control problems (Allen & McKenna, 2017).

- **Operational and Human Risks:** Loading docks experience more temperature excursions because improper handling, inadequate packing, and extended time in ambient temperatures during unloading create temperature control problems (Ren, 2024).

- **External and Environmental Risks:** The thermal packaging limits of shipments get exceeded because of logistical bottlenecks and unexpected transport delays (Ahmed et al., 2025).

3.3. Applying Quality Risk Management (QRM) to the Cold Chain

The second chapter explained the theoretical foundations of Quality Risk Management (QRM). However, applying this framework to temperature-controlled logistics solves a critical industry problem. The industry usually enforces QRM strictly inside the manufacturing plant, but researchers identify a dangerous lack of QRM application during active supply chain and distribution operations (Kumar & Jha, 2018). Because of this problem, QRM for pharmaceutical distribution needs to change from a broad philosophy into practical daily operational procedures which protect Time- and Temperature-Sensitive Pharmaceutical Products (TTSPPs). The supply chain managers must adapt each phase of QRM to address the unique physical vulnerabilities of the cold chain using the four-step cycle from international guidelines (ICH, 2023).

- **Practical Risk Assessment:** The managers must evaluate transport durations against specific temperature parameters to calculate a risk-based assessment of exposure times. This process determines exactly how much thermal stress the product can survive before it exceeds its safe limits (GCCA, 2024).

- **Proportional Risk Control:** The financial resources and technology which they use for control must match the severity of the risk according to the QRM principle of proportionality (ICH, 2023).

- **Inter-Organizational Risk Communication:** Risk communication in the cold chain mostly happens through strictly defined and written transportation procedures. These procedures establish the cooperative effort between the shipper, loader, carrier, and receiver (GCCA, 2024).

- **Continuous Risk Review and Incident Response:** Organizations must conduct a thorough investigation using manufacturer stability data to decide the final disposition of the product. The organization uses this feedback to implement Corrective and Preventive Actions (CAPA) which protects against future logistical breakdowns (GCCA, 2024).

3.4. Mitigation and Monitoring Technologies

Pharmaceutical companies need to adopt advanced digital tools because conventional risk management methods fail to protect products until dangerous situations have already developed. The cold chain system needs modern technological solutions because its physical weaknesses exist despite companies' adherence to Quality Risk Management (QRM) standards. The managers need to establish a connection between physical logistics design and digital tools. This combination enables distribution networks to maintain environmental sustainability and complete traceability while protecting against unanticipated disruptions (Martínez, 2025).

Table III: Digital Technologies for Mitigation and Monitoring in Pharmaceutical Cold Chains

Technology	Operational Function	Reference
Real-Time Monitoring with IoT Devices	Companies now use IoT and RFID technologies instead of basic thermal data loggers to track environmental conditions throughout the entire shipping process. IoT sensors connect with warehouse management systems and activate alarms when temperature shifts occur, providing immediate visibility to protect medicine from destruction.	(Wang, 2025)
Traceability and Security through Blockchain	Blockchain technology creates a digital ledger that permanently records temperature measurements and location changes, solving trust and transparency issues between partners. When combined with Digital Twin technology, it enables faster detection of logistical anomalies and provides a complete verified operational record.	(Schouten et al., 2025)
Predictive Risk Mitigation using Machine Learning	Machine Learning algorithms analyze historical supply chain data and past temperature deviations to predict future transportation weaknesses. Studies show implementation reduces temperature deviations by 25 percent and operational logistics costs by 20 percent.	(Chowdhury, 2025)

Source: Compiled by the author based on Wang (2025), Schouten et al. (2025), and Chowdhury (2025).

Chapter Conclusion

This first chapter successfully established the theoretical foundations necessary to understand the complex challenges of risk management within the pharmaceutical cold chain. By combining a thorough literature review with a structured conceptual framework, we defined the core components of temperature-controlled distribution and highlighted the strict handling requirements for Time- and Temperature-Sensitive Pharmaceutical Products (TTSPPs). Additionally, we identified the primary physical, operational, and environmental risk typologies, and detailed the methodological tools required to assess and control them.

The exploration of frameworks like Quality Risk Management (QRM) and Supply Chain Risk Management (SCRM) emphasized the critical need for a proactive, integrated approach. This is especially true when adapting global standards to specific, real-world operational realities, such as the infrastructural constraints within the Algerian setting. Furthermore, we demonstrated that when these theoretical models are combined with modern technological innovation such as IoT monitoring, Blockchain traceability, and Machine Learning they offer highly concrete solutions to prevent disruptions and strengthen the overall resilience of the distribution network.

Ultimately, this strong theoretical baseline will serve as the primary reference framework for the empirical field analysis presented in the upcoming chapters. The concepts established here will directly guide our understanding of current logistical practices and help us accurately evaluate the existing risk management systems utilized at the Central Pharmacy of Hospitals (PCH) - Annaba Annexe.

CHAPTER II: ORGANIZATIONAL CONTEXT AND METHODOLOGICAL FRAMEWORK

This second chapter is dedicated to the detailed presentation of the methodology adopted for this research, the risk management tools utilized, and the host organization within which this study takes place. This step is essential to ensure the scientific rigor and coherence of our approach while establishing a clear framework for data analysis.

First, we will explain the methodological approach followed, specifying the interpretative paradigm that guides our research. We will also present the various data collection and analysis methods used namely semi-structured interviews, document analysis, and direct field observation to guarantee the relevance and reliability of the gathered information. These elements are fundamental for understanding how the obtained results were constructed and interpreted by operational actors.

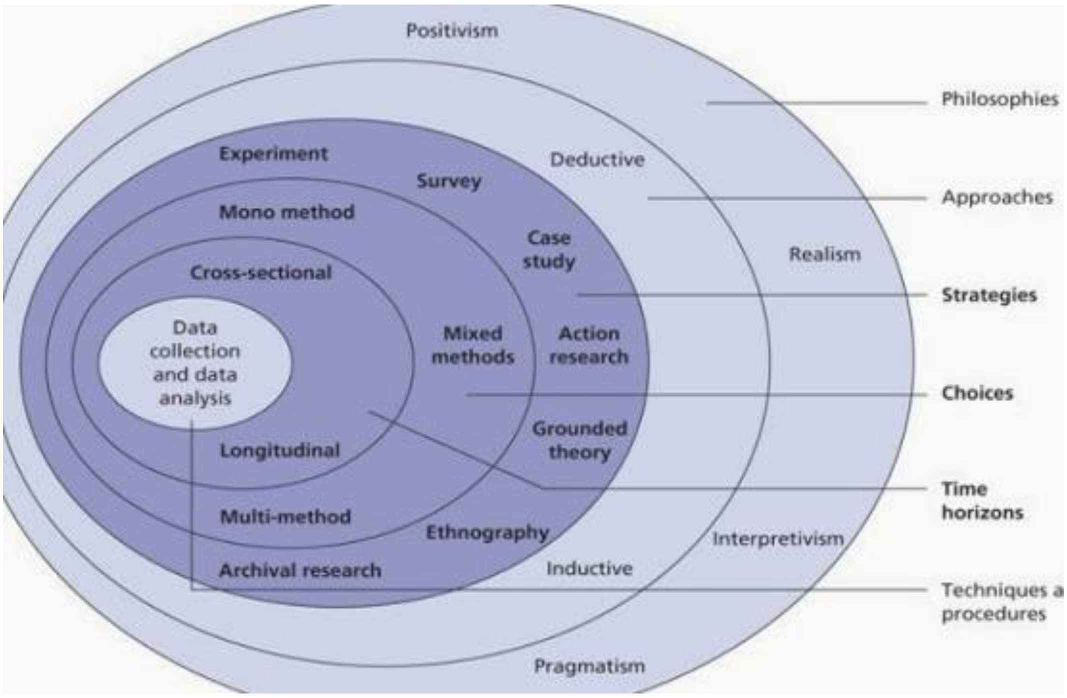
Second, we will describe the main risk management tools and techniques employed in this research, such as the Ishikawa diagram, risk matrix , FMEA, and CAPA. These tools enable the identification, analysis, quantification, and treatment of vulnerabilities specific to the logistics of thermosensitive products.

Finally, we will dedicate a section to presenting the host organization, the Central Pharmacy of Hospitals (PCH), and its Annaba Annex. This presentation will help to better contextualize the empirical framework in which this study is situated, as well as the specificities of the studied distribution circuit. This contextualization is indispensable for a complete understanding of the practical work developed in the following chapter.

SECTION 01: Methodological Framework

A structured, rigorous, and systematic approach to inquiry is necessary for studying complex organizational phenomena. Scientific research provides exactly this foundation, enabling researchers to use structured methods to examine phenomena, solve problems, and derive valuable results. Research goes beyond mere data collection to fulfill its intellectual mission: describing existence, interpreting its meaning, understanding its causes, and forecasting its future development. It is upon this scientific tradition that the subsequent methodological framework has been built.

Figure 3: Research onion



Source : Ren 2024

1. Research Design and Epistemological Framework

The study requires a comprehensive approach that goes beyond basic statistical analysis to address the complex challenges of pharmaceutical cold chain management at the Central Pharmacy of Hospitals (PCH) in Annaba. A structured qualitative methodology is adopted (Creswell & Poth, 2018).

Qualitative research does not aim to quantify or measure phenomena, but rather to collect verbal and narrative information that supports an interpretative analysis. This broad term encompasses various theoretical and methodological approaches, as well as diverse methods of data collection and analysis (Aubin-Auger et al., 2008). According to Creswell (2014), qualitative research is conducted in a natural setting where the researcher himself serves as the primary instrument of data collection, gathering both textual and visual data. It favors inductive analysis and seeks to interpret the meanings that participants construct from their lived experiences in the field.

The management of thermosensitive logistics involves more than mechanical refrigeration, as it is also shaped by organizational structure, human behavior, and the prevailing regulatory framework. An interpretive approach is therefore employed through a single case study to develop an in-depth understanding of the PCH Annaba distribution network (Walsham, 1995).

1.1. Epistemological Stance: The Interpretative Paradigm

Within the realm of supply chain and pharmaceutical logistics, this study is anchored in the interpretative paradigm (Ponelis, 2015; Walsham, 1995). It is acknowledged that positivist approaches hold considerable value in other cold chain studies particularly those employing statistical process control or quantitative performance modeling. However, a positivist framework proves insufficient here, because the unit of analysis is not a controlled experimental variable, but rather an organization's behavioral and procedural ecosystem. Interpretativism recognizes that organizational reality is socially constructed by the actors operating within it, and therefore cannot be fully captured through universal mathematical laws alone (Walsham, 1995).

The primary data collected from PCH Annaba reveals that temperature excursions are rarely just equipment failures; they are often the result of complex human interactions, such as workarounds during truck unloading, the complete absence of formalized procedures, and a general lack of risk management awareness among the staff.

By adopting an interpretative stance, this research assumes an inductive logic (Saunders, Lewis, & Thornhill, 2019). The objective is not to test abstract statistical probabilities, but to deeply understand the operational reality of the logisticians, pharmacists, and drivers on the ground (Walsham, 1995). Importantly, this inductive logic governs the data collection phase and directly informs the qualitative severity and probability estimations subsequently used to populate the risk analysis framework. Specifically, the insights extracted from the field inductively feed into the structured FMEA (Failure Mode and Effects Analysis) risk matrix, ensuring that Corrective and Preventive Actions (CAPA) are grounded in the lived operational context rather than abstract assumptions. This epistemological choice perfectly justifies the reliance on a qualitative approach for data collection and risk prioritization (Creswell & Poth, 2018; Ponelis, 2015).

1.2. Research Nature: An Exploratory and Descriptive Case Study

The research requires in-depth understanding of particular operational environments which leads to its selection of qualitative case study research design (Ponelis, 2015; Walsham, 1995). The study achieves complete operational understanding through its dedicated examination of all logistical challenges that face PCH Annaba.

While statistical generalization is not the aim of this single-case design, the findings are intended to contribute to analytical generalization by refining theoretical propositions applicable to similar public pharmaceutical distribution networks (Yin, 2018). The goal is therefore to generalize to theoretical frameworks and risk management models, not to broader populations.

Furthermore, the nature of this research is twofold:

- **Exploratory:** Risk management protocols specifically dedicated to the cold chain at the Annaba branch have not yet been exhaustively formalized. An exploratory approach is necessary to uncover the hidden vulnerabilities and informal practices that currently exist within the facility (Ponelis, 2015).

- **Descriptive:** Following the exploration, the research systematically describes the current state of the supply chain, mapping out the precise flow of thermosensitive medicines from reception to final distribution (Saunders, Lewis, & Thornhill, 2019).

1.3. Methodological Triangulation

The research adopts methodological triangulation (Creswell & Poth, 2018; Ponelis, 2015) to maintain scientific accuracy and data integrity throughout the interpretative case study research. A strong evidence base is constructed through the convergence of multiple qualitative data sources (Walsham, 1995), as follows:

- **Document Analysis:** Examination of official PCH documents, including mandates, standard operating procedures (SOPs), and temperature records.Document analysis is employed as a systematic qualitative method to interpret and extract meaning from these textual data sources (Bowen, 2009).

- **Direct Observation:** On-site observation of product handling practices and cold room conditions at the Annaba facility.This method allows the collection of real-time, contextual data on actual practices within the natural setting (Kawulich, 2005).

- **Semi-Structured Interviews:** Semi-structured interviews served as the primary data source, allowing participants to share expert assessments and operational realities while giving the researcher flexibility to explore emerging themes (DeJonckheere & Vaughn, 2019).

2. Data Collection Tools and Techniques

To gain a clear and detailed understanding of the risk management environment at PCH Annaba's cold chain, this study used qualitative data collection methods. Since PCH Annaba is mainly responsible for the distribution and storage of temperature-sensitive pharmaceutical products rather than manufacturing them, the data collection tools were designed to match the real-life context of logistical operations, regulatory compliance, and storage conditions.

2.1. Semi-Structured Interviews

The foundational instrument for qualitative data gathering within this interpretative research was the semi-structured interview. Positioned between an entirely open conversational format and a rigid structured questionnaire, this technique enables the researcher to steer discussions toward targeted logistical themes while simultaneously affording respondents the latitude to articulate their professional experiences, perceptions, and systemic observations with depth and authenticity (Saunders, Lewis, & Thornhill, 2019).

To ensure the validity and relevance of the qualitative data, we adopted an iterative, funnel-based approach during the data collection phase (Saunders et al., 2019). Instead of following a rigid and fixed protocol, this flexible method allowed us to continuously refine the interview questions based on what we learned from the initial field visits. This helped us better adapt the process to the real operational realities at PCH Annaba (Yin, 2018).

2.1.1. Objectives and Construction of the Interview Guide

Instead of relying on a single, static interview guide, the qualitative data collection was structured into two consecutive interview phases.

- **Phase 1 :** A comprehensive 37 question guide (Appendix A and B). The primary purpose of this first phase was to facilitate a macro-level mapping of the distribution network and to assess the formal Quality Management System (QMS) procedures from a management perspective.

- **Phase 2 :** A targeted 9 question guide (Appendix C). The purpose of this second phase was to capture the micro-level reality on the warehouse floor, focusing strictly on daily logistical constraints, physical capacities, and practical emergency reactions.

To ensure a comprehensive analysis, both of these tailored interview guides were built around the same three overarching themes:

- **Daily Operations and Coordination:** Covering the procedural management of thermosensitive products across all stages, including receipt, storage conditions, inter-service communication, and outbound dispatching protocols.

- **Risk Management and Emergency Response:** Examining the continuous monitoring mechanisms in place and the crisis procedures activated in response to thermal deviations or recorded non-conformities.

- **Infrastructure, Resources, and Institutional Awareness:** Evaluating the operational reliability and structural adequacy of cold chain assets, as well as gauging the degree of risk culture and formal training embedded within the staff.

2.1.2. Structure and Administration of the Interviews

All interview sessions were conducted in person within the PCH Annaba premises. A standardized structure was applied consistently across all sessions to uphold methodological reliability:

- **Opening Phase:** Brief introduction of the research scope, provision of confidentiality assurances, and collection of informed verbal consent from the participant.

- **Core Discussion Phase:** Systematic exploration of the three thematic clusters, with targeted follow-up prompts designed to draw out concrete, experience-based operational examples.

- **Closing Phase:** A final invitation for participants to raise any unaddressed challenges, followed by acknowledgments and conclusion of the session.

Each interview extended over a period of **30** to **45 minutes**. This duration was determined to be sufficient for meaningful exploration of the three thematic blocks without inducing respondent fatigue, in line with best practices for professional interview contexts (Saunders et al., 2019). With the informed and explicit consent of all participants, sessions were audio-recorded to ensure verbatim transcription accuracy and to preserve the integrity of contextual nuances that written note-taking alone may fail to capture (Creswell & Poth, 2018)

2.1.3. Profile of Respondents

To fully understand the cold chain, a purposive sampling strategy was adopted. Participants were intentionally selected based on their direct involvement in cold chain activities and their expertise in pharmaceutical distribution operations. This selection allowed us to compare official management practices with the actual daily working conditions on the ground. Employees occupying both strategic and operational positions were therefore included in the study to provide a comprehensive understanding of the system.

We started the first phase with seven employees to get a complete picture of the entire system. However, for the second phase, we reduced the group to five core employees. We excluded two profiles, the Truck Driver and the Cold Room Technician because their jobs do not involve the daily, internal handling of the medicines inside the warehouse.

Table IV: Profile of Interview Respondents

Respondent	**Primary Responsibilities**	**Rationale for Selection**	**Duration**
Technical Assistant Pharmacist	Responsible for handling control, data recording via data loggers, traceability, and ensuring the prioritized unloading and dispatch of thermosensitive medicines.	Selected to provide critical insights into electronic temperature monitoring, risk mapping history, and quality compliance procedures during the immediate transfer of products.	45 min

Head of the Operations Department	Manages the storage and distribution structure, organizes annual product flow planning, and monitors/sensitizes storekeepers on good handling practices.	Selected to offer a strategic, macro-level perspective on inter-departmental coordination, distribution scheduling, and overall system infrastructure management.	45 min
Head of Thermosensitive Medicines	Processes and validates monthly client orders based on stock availability while strictly maintaining cold chain conservation conditions.	Selected for her expertise in order management, product flow scheduling, and the handling of systemic vulnerabilities such as overstock situations.	35 min
Receiving Manager	Receives incoming thermosensitive medicines, carries out sorting and calibration, establishes receipt reports, and enters data into the information system.	Selected to evaluate the initial risks at the point of delivery, including off-hours unloading procedures, transit delays, and reception bottlenecks.	35 min
Storekeeper	Handles physical storage organization (applying the FEFO principle), controls temperatures at each step, and ensures traceability inside the cold rooms.	Selected to provide direct, hands-on data regarding physical cold room capacities, daily door-opening risks, and practical emergency responses to alarms	35 min
Cold Room Technician	Responsible for the mechanical maintenance, repair, and operational integrity of the cooling units.	Selected to assess the technical infrastructure, routine maintenance protocols, and the mechanical reliability of the cold storage units.	30 min
Truck Driver	Responsible for the physical transportation and safe delivery of thermosensitive medicines from the central supplier in Algiers to the Annaba Annex.	Selected to evaluate upstream transit risks, potential temperature excursions during long-distance transport, and coordination challenges upon arrival at the facility.	3O min

Source: Developed by personal efforts.

This sample size is highly appropriate for a qualitative case study approach. Theoretical saturation was explicitly confirmed by the fourth interview (Saunders et al., 2023), as the information collected after this point did not generate any new logistical risk categories.

This data stabilization provided clear evidence that sufficient empirical data had been gathered to fully meet the exploratory objectives of the study (Creswell & Poth, 2018).

2.2. Document Analysis

Building upon this theoretical exploration, the document analysis consists of examining texts and reports produced by the organization to compare field practices against formal processes and identify any potential gaps. In the context of this research, the objectives of the documentary collection are twofold:

First, a primary source of our documentary research involved consulting external and international normative frameworks. We consulted specialized literature, scientific articles, and reference standards such as ISO 31000 for risk management, Good Distribution Practices (GDP), and World Health Organization (WHO) guidelines relating to the management of thermosensitive products. These documents provide the essential normative baseline to evaluate PCH's operational compliance.

Second, internal company documents were analyzed to better understand concrete risk management practices. This documentation allowed us to cross-reference the information gathered during the semi-structured interviews, verifying the consistency between the respondents' statements and the technical records, thereby effectively preparing for the field investigation phase.

2.2.1. Types of Internal Documents Analyzed

To maintain methodological focus, the selection was restricted to documents directly illustrating the management of the cold chain:

- **Technical Directives and Instructions:** The internal rules governing temperature control during storage and transport, including specific operational guides like the instruction for handling temperature recorders (INS-TRG-02).

- **Strategic and Management Records:** High-level documents, such as the management review report (FOR-GOV-03) and the technical-regulatory risk map (FOR-SMQ-22), which demonstrate how leadership views and prioritize systemic vulnerabilities.

- **Control and Compliance Proof:** Official directives like the ANPP (National Agency of Pharmaceutical Products) note on traceability, alongside independent calibration certificates issued by VERITAL to verify the cold rooms. We also reviewed the technical-regulatory process flowchart (PRS-TRG-01).

- **Operational and Empirical Data:** An extensive Excel database of continuous temperature logs, physical stock cards, and the internal forms used to officially declare temperature deviations (FOR-TRG-09).

2.2.2. Document Selection Criteria

To ensure our analysis remained rigorous and focused, we applied strict inclusion criteria when collecting documents from the Annaba annex's technical and logistical departments:

- **Relevance:** We filtered out general administrative files, retaining only the documents directly tied to cold chain integrity, quality processes, and risk management.

- **Recency:** We focused on recent records (2018–2026) to ensure our findings accurately reflect current equipment, staff practices, and active regulations.

- **Representativeness:** We selected documents that cover the entire logistical journey from the moment a truck arrives at the receiving dock, through extended storage, to the final handover to healthcare facilities.

The document analysis achieved its methodological goal because it supplied all the necessary factual and technical evidence which allowed researchers to create a current operational framework for PCH Annaba. By cross-referencing these written records with the declarations gathered during the interviews, we established a highly objective foundation. The complete dataset establishes a connection between theoretical procedures and actual field operations which enables researchers to conduct a detailed assessment of the organization's risk management system throughout the following analytical sections.

2.3. In-Depth Case Study and Field Observation

To validate the formal procedures identified during the document analysis, this research adopted a single case study approach. As (Yin, 2014) emphasizes, the case study is a preferred methodology for deeply exploring a complex phenomenon within its real-world context. By applying this framework to the PCH Annaba annex, we were able to extract detailed insights into the daily interactions between logistical actors, technical processes, and physical infrastructure.

In addition to interviews and document analysis, unstructured direct observation was conducted throughout the field internship. This immersion enriched our understanding of organizational behaviors, specifically regarding how staff react to sudden infrastructural anomalies and the informal adjustments made in real-time to secure thermosensitive supplies.

2.3.1. Observation Techniques

To capture these operational realities and reconstruct daily logistical flows, several field observation techniques were actively deployed:

- **Direct Field Observation:** Continuous monitoring at the loading dock and storage zones to observe the physical handling of thermosensitive medicines. This included observing the exact procedures executed by the staff when client-provided vehicles arrived to take possession of the pharmaceutical lots.

- **Process and Anomaly Tracking:** Observing staff behavior and operational dynamics during routine operations as well as during unexpected infrastructural anomalies, specifically noting containment strategies and the timeline of corrective actions.

- **Informal Stakeholder Interactions:** Engaging in unstructured discussions with logistical actors on the ground such as external transport drivers and internal technical staff. These informal interactions were crucial for uncovering systemic realities and operational nuances that are not explicitly detailed in official manuals.

3. Analytical Tools and Methods

The processing of the collected data required specific analytical frameworks suited to qualitative field research. This section details the exact methods used to examine the information gathered during the internship at PCH Annaba.

3.1. Qualitative Analysis and Thematic Coding (NVIVO)

To analyze the data collected through semi-structured interviews, thematic analysis was selected as the main analytical method. This approach is commonly used in qualitative research to identify patterns and recurring themes within interview transcripts or documents. It allows researchers to organize participants' responses into meaningful categories and to highlight repeated operational issues and experiences (Fallery, 2007).

To support this process, NVivo software was used. NVivo is a qualitative data analysis (QDA) tool that helps researchers organize, code, and examine non-numerical data such as interview transcripts. By assigning codes (nodes) to specific segments of text, the software improves the organization and transparency of the analysis. It also makes it easier to explore relationships between themes within large amounts of textual data (Jackson & Bazeley, 2019; Zha, 2022).

3.1.1. The Hybrid Coding Strategy

The coding procedure followed a hybrid approach. The initial coding framework was based on the theoretical interview guide (a deductive approach), while remaining completely open to new, unexpected root causes and operational vulnerabilities emerging directly from the participants' answers (an inductive approach).

3.1.2. Steps of NVivo Data Analysis

The practical execution of the data analysis followed six systematic steps to ensure accuracy and methodological consistency:

Data Preparation: The interview audio recordings were meticulously transcribed and formatted into text documents.

Importing into NVivo : All finalized transcripts were uploaded into the NVivo software environment to create the primary dataset.

Exploratory Lexical Analysis: Before detailed coding began, a word frequency query was run to visualize the most dominant vocabulary used by the participants, providing an initial macro-level view of their operational priorities.

Thematic Coding: Analytical “nodes” were created and assigned to specific text segments based on the key **logistical causes** identified in the transcripts.

Thematic Analysis: The qualitative data was grouped by recurring themes to identify central patterns related to **the root causes of cold chain ruptures**.

Visualization: The visual representation of the NVivo findings was intentionally targeted. A word frequency cloud was generated to visually highlight the dominant operational vocabulary, and a hierarchical matrix of the thematic nodes was extracted to summarize the reference frequencies. These specific outputs were sufficient to systematically prepare the data for the root-cause analysis (Ishikawa) presented in the subsequent results chapter.

4. Risk Management tools

To translate qualitative findings into measurable logistical improvements, a structured multi-tool methodology was adopted. No single analytical tool can fully capture the complexity of a pharmaceutical cold chain. Therefore, a sequential combination of four distinct risk management tools was employed to identify, prioritize, quantify, and treat the infrastructural vulnerabilities at the PCH Annaba annex.

Within the framework of this research, these tools were mobilized for their complementarity, analytical rigor, and capacity to transform qualitative data into actionable insights. Their use aligns with ISO 31000 compliant risk management principles and offers several key advantages: systematic and reproducible evaluation, effective decision support and prioritization, improved traceability, and the strengthening of an institutional risk culture (ISO, 2018; Hopkin, 2018; IRM, 2012).

4.1. Tools Mobilized for Risk Analysis, Evaluation, and Treatment

Within this study, four risk management tools were selected for their complementarity, analytical rigor, and ability to provide a progressive understanding of the qualitative data collected. These tools were applied to analyze and address logistical vulnerabilities affecting the cold chain integrity of thermosensitive medicines.

Table V: Risk Management Tools

Tool	Purpose in the Study
6M Analysis (Ishikawa Diagram)	Applied to identify and structure the root causes of cold chain disruptions utilizing the 6M categories: Manpower, Methods, Machine, Material, Milieu, and Measurement.
Risk Matrix	Used to evaluate risk criticality by crossing probability and severity and to synthesize AMDEC results into a visual heatmap for decision-making.
FMEA	Applied to identify failure modes and calculate Risk Priority Numbers (RPN) based on Severity, Occurrence, and Detectability scoring.
CAPA	Applied to convert the critical risks prioritized by the FMEA into strict action plans. It defines corrective measures to fix immediate logistical anomalies, and preventive protocols to eliminate their root causes, ensuring continuous compliance within the cold chain.

Source: Developed by personal efforts.

Section 02: Presentation of the Host Organization

Before proceeding to the analysis of the results, it is essential to present the organizational context in which this research takes place: the Central Pharmacy of Hospitals (PCH) and, more specifically, its Annaba Annex.

1. Presentation of the PCH:

The Central Pharmacy of Hospitals (PCH) has operated as a Public Establishment with an Industrial and Commercial Character (EPIC) since its establishment on September 25, 1994, through Executive Decree No. 94-293. The PCH delivers pharmaceutical products to public healthcare institutions throughout the entire national territory, functioning as the main supplier for these establishments under the supervision of the Ministry of Health.

The PCH operates under a multifaceted mandate which requires it to balance commercial and industrial goals with essential public service responsibilities. The organization maintains the emergency ORSEC stock, which functions as a national strategic reserve.

The organization must ensure product availability and suitable storage conditions while achieving cost efficiency in order to deliver reliable service to its 1,000 client facilities.

The PCH operates a decentralized distribution network which delivers services through five regional hubs located in the three northern cities of Algiers, Oran, and Annaba, and the two southern cities of Biskra and Bechar. The organization maintains its supply chain through 250 preferred suppliers, which include 89 local suppliers and 158 international partners. Furthermore, the PCH plans to make direct investments in the domestic pharmaceutical industry as part of its strategic goal to decrease national reliance on global market resources.

A General Manager leads the PCH, while a Board of Directors controls its operations. This supervisory board consists of representatives from various ministries and is chaired by the Minister of Health.

Table VI: The Central Hospital Pharmacy in numbers

Employes	**Annexes**	**Clients**	**Suppliers**	**Marketed products**
More than **1000**	**05**	**621** public's health establishments, **1396** various clients	**89** Local suppliers, **158** Foreign suppliers	**1760**

Source : PCH website (Pharmacie Centrale des Hôpitaux)

1.1. PCH Core Activities and Departments

The PCH operates through three main operational pillars which include procurement, storage, and distribution activities. The core functions of the organization require multiple directorates to deliver their specialized expertise for successful execution.

1.1.1. Technical and Regulatory Directorate (DTR)

The DTR ensures strict adherence to pharmaceutical regulations and quality standards. The directorate maintains complete control over the product lifecycle—from initial receipt until final distribution—through the presence of pharmacists who work at every location. Their responsibilities include verifying import authorizations at customs, collaborating with national health laboratories for batch release, ensuring cold chain integrity during transit, and conducting post-market pharmacovigilance to monitor for adverse effects.

1.1.2. Procurement Directorate

This department serves as the primary purchasing organization which controls all buying activities for both domestic and international markets. The directorate manages its complete purchasing process through product family divisions which handle contract creation, bank domiciliation, supplier negotiations, and the resolution of purchasing legal disputes.

1.1.3. Commercial Directorate

The commercial team maintains economic viability for the organization because the PCH holds EPIC status. The directorate monitors market trends together with client demand evaluation to develop operational procurement and distribution methods that efficiently serve healthcare facilities' requirements.

1.1.4 Storage and Inventory Management

This department functions as an essential unit which maintains product quality while maximizing warehouse storage capacity. The team uses stock rotation principles through their implementation of the First Expired, First Out (FEFO) method to prevent stock outs and decrease inventory waste. The organization oversees secure storage operations which include both national strategic reserves and ORSEC reserves.

1.1.5 Logistics Directorate (DML)

The DML serves as the operational engine of the PCH. The organization controls core logistical operations which include transporting pharmaceutical goods, managing its entire vehicle fleet, handling customs transit, and acquiring technical equipment for its internal departments.

1.1.6 IT and Information Systems Directorate (DISI)

The digital infrastructure of the PCH is developed and secured by the DISI. The directorate manages network security operations while creating specific software programs which support inventory and administrative functions. Additionally, they use statistical data modeling to enable executive management to make decisions based on evidence.

1.1.7 Management Control Directorate

The Management Control department serves as the main body which oversees both financial matters and operational activities, working together with all departments to create their yearly budget plans. The team uses statistical analysis to monitor how actual performance compares with strategic forecasts, tracks operational deviations, and prepares the necessary reports for Board of Directors meetings.

1.2. Missions, vision and objectives of the PCH

1.2.1. Missions

As part of the national health policy, the central pharmacy has the mission:

- To supply public health establishments with pharmaceutical products and medical devices, within the framework of the procurement procedure on behalf of these establishments. The list of products is determined by a decision of the minister in charge of health.
- To develop and implement supply programs based on national production.
- To develop an import program for pharmaceutical products based on the national needs expressed by the ministry in charge of health.
- To market pharmaceutical products for the benefit of public and private healthcare institutions.
- To market pharmaceutical products to authorized establishments responsible for the distribution of pharmaceutical products and pharmacies.
- To carry out the execution of regulatory actions for the supply of pharmaceutical products, in accordance with the current legislation and regulations.
- To manufacture medicines, particularly generic medicines.
- To proceed with the packaging of pharmaceutical products.
- To establish retail points of sale for pharmaceutical products intended to ensure the availability of products across the national territory.

- To provide technical assistance, within the framework of a partnership, to any operator involved in the pharmaceutical industry.
- To carry out public service obligations set out in Article 4 bis in accordance with the specifications attached to the decree.

And within the framework of public service obligations, the central pharmacy is responsible for:

- To hold a strategic stock of pharmaceutical products.
- To hold an ORSEC stock of pharmaceutical products stopped by the ministry responsible for health.
- To supply public health establishments with pharmaceuticals intended for the treatment of rare diseases and life-threatening conditions. The lists of diseases and pharmaceutical products concerned are established by decree of the minister in charge of health.
- To supply public health establishments with pharmaceuticals, as part of national prevention programs and national health plans, as well as related pharmaceuticals, is determined by an order from the minister in charge of health.

1.2.2 Vision

The Central Pharmacy of Hospitals ultimately aims to invest commercially in meeting the needs of public health establishments for pharmaceutical products and increasing its market share. Furthermore, the PCH also plans to improve its management of the supply program in terms of the triptych of cost, time, and quality; reduce its import bill by opting for domestic production; optimize inventory, control transit costs, and modernize sites and equipment. In terms of quality management, the PCH also plans to improve its quality management in terms of compliance with pharmaceutical product regulations. In terms of safety, it is understood that the development of a safety culture within the PCH, the modernization of the existing safety system, and the strengthening of intervention and protection measures will be undertaken.

To achieve this vision, a reorganization of human resources is being implemented, supported by the development of communication aspects both internally and externally, and the mass introduction of modern technologies and decision support tools to reach its objectives effectively and efficiently.

1.2.3. Objectives

- First, satisfy all requests within a contractual framework for pharmaceutical products under the conditions of quality, costs, and throughout the entire national territory.
- Ensure the availability of products intended for specific national health programs that may be decided by the Ministry of Health, Population, and Hospital Reform.
- The PCH's role is to ensure and monitor the proper management of pharmaceutical products by overcoming any existing obstacles.

SOURCE : PCH website (Pharmacie Centrale des Hôpitaux).

1.3. Annex of Annaba

The Central Pharmacy of Hospitals, Annex of Annaba, was created by ministerial decision dated March 31, 1996, following a deliberation of the Board of Directors meeting on March 27, 1996.

Located in the municipality of El-Bouni, on the El-Hadjar road, it occupies the site of the former ASWAK and consists of an administrative block and two warehouses; the entire area spans one hectare, forty-seven Ares, and twelve centiares.

Composed of two levels, the administrative block is divided into sixteen (16) offices covering a developed area of 500 m².With an area of 3427 m², the warehouses are composed of various storage units including:

- Medicine Store
- Medical device store
- Psychotropic store

- Chemical store
- 03 cold rooms
- Four (04) offices
- Chamber of Narcotics

All of these warehouses offer a storage capacity of 1800 pallet positions.

There was an extension in the industrial zone of Berrahal with the acquisition of the site of the dissolved former company Digromed, covering an area of 85,000 m², acquired under a concession dated 09/11/2017.

The massive and accessory solute products are stored inside a 13,000 m² warehouse.

The activity of the Annaba Annex extends over a large part of the eastern region of the country and covers 11 Wilayas for 352 establishments distributed as follows:

- 11 DSP
- 03 University Hospital Centers (CHU)
- 01 Cancer Center (CAC)
- 01 Military Hospital (5th Military Regions)
- 01 Center CSSM 5RM
- 01 Military Direction 5RM
- 02 EH
- 19 EHS
- 52 E.P.H
- 54 E.P.S.

1.3.1. PCH Organizational Structure

The organizational structure of the PCH Annex in Annaba is designed to integrate pharmaceutical expertise with complex logistical and administrative functions. This hierarchical framework ensures clear accountability across departments, from technical pharmacy management to cold chain operational units. The detailed organizational chart, illustrating the various services and reporting lines, is provided in Appendix [D].

1.3.2. Distribution Circuit and Risk Management

To ensure product quality and guarantee full traceability, the journey of these thermosensitive medicines goes through three carefully controlled phases**:**

- **Reception:** As soon as the shipments arrive from Algiers, the staff immediately unloads the medicines directly into cold rooms to protect the cold chain. They create a technical reception note and check the transit temperature monitors to make sure the products stayed perfectly cool during the entire trip.

- **Storage:** Next, the storekeeper physically verifies the inventory, and the admin team logs it into the central IT system. The medicines are organized using the FEFO rule (First Expired, First Out) to prevent any waste.

- **Distribution:** Finally, client orders are processed based on a set monthly schedule. However, the PCH’s responsibility doesn't just stop at the door. To make sure the medicines stay secure after they leave the facility, clients are strictly required to pick up their orders using their own verified cold-transport, like a refrigerated truck or insulated boxes. (Appendix M)

Chapter conclusion

In conclusion, this second chapter has established the methodological and contextual foundations essential to our research. The first section justified the choice of a qualitative approach and a case study, while precisely structuring the data collection tools and analytical risk assessment methods (Ishikawa , Risk matrix , FMEA and CAPA). The second section complemented this theoretical framework with a detailed description of the Central Pharmacy of Hospitals and its Annaba Annex. This in-depth understanding of the logistical environment, combined with a rigorous diagnostic methodology, now provides us with all the necessary groundwork to process the collected data. This naturally leads us to the next chapter, which will be dedicated to the presentation, analysis, and discussion of our empirical results.

CHAPTER III: RESULTS AND DISCUSSION

This third chapter transitions from our methodological framework to the empirical core of the research. It is structured into two parts: Section one presents the field data and the quantitative risk assessment (FMEA and CAPA), while Section two critically discusses these logistical vulnerabilities against the theoretical models established in the literature review.

Section 01: Results of the Study

This section presents the primary data collected at the PCH Annaba Annex, moving systematically from qualitative observation to quantitative risk evaluation. By utilizing NVivo thematic analysis, the Ishikawa diagram, and the FMEA matrix, we identify the root causes of cold chain disruptions and translate them into a concrete Corrective and Preventive Action (CAPA) plan.

1. Execution of the Interview Strategy and General Findings

The data collection followed a funnel-based method carried out through an iterative process, as explained in the methodological framework. Although the structure of the two phases was presented in the previous chapter, their practical implementation in the field generated two distinct but complementary sets of findings.

The first phase involved a detailed 37-question guide (Appendix A) administered to seven staff members. Crucially, this group encompassed a diverse cross-section of roles, ranging from strategic-level management (such as the Pharmacist and the Head of the Operations Department) to operational supervisors like the Receiving Manager. This phase provided a broad overview of PCH Annaba's distribution system. The findings showed that cold chain risk management mainly depends on informal practices based on professional experience. While management appears competent, there is no formally structured ISO-compliant Quality Management System specifically governing cold chain procedures.

The second phase relied on a shorter nine-question guide (Appendix C). Similarly, this phase involved a diverse mix of personnel interacting with the warehouse environment including operational floor staff such as storekeepers, receiving technicians, and external participants like truck drivers to ensure the operational reality was captured from multiple organizational angles. This stage revealed the daily reality inside the warehouse, particularly limitations related to storage capacity, resource shortages, and mainly reactive emergency responses.

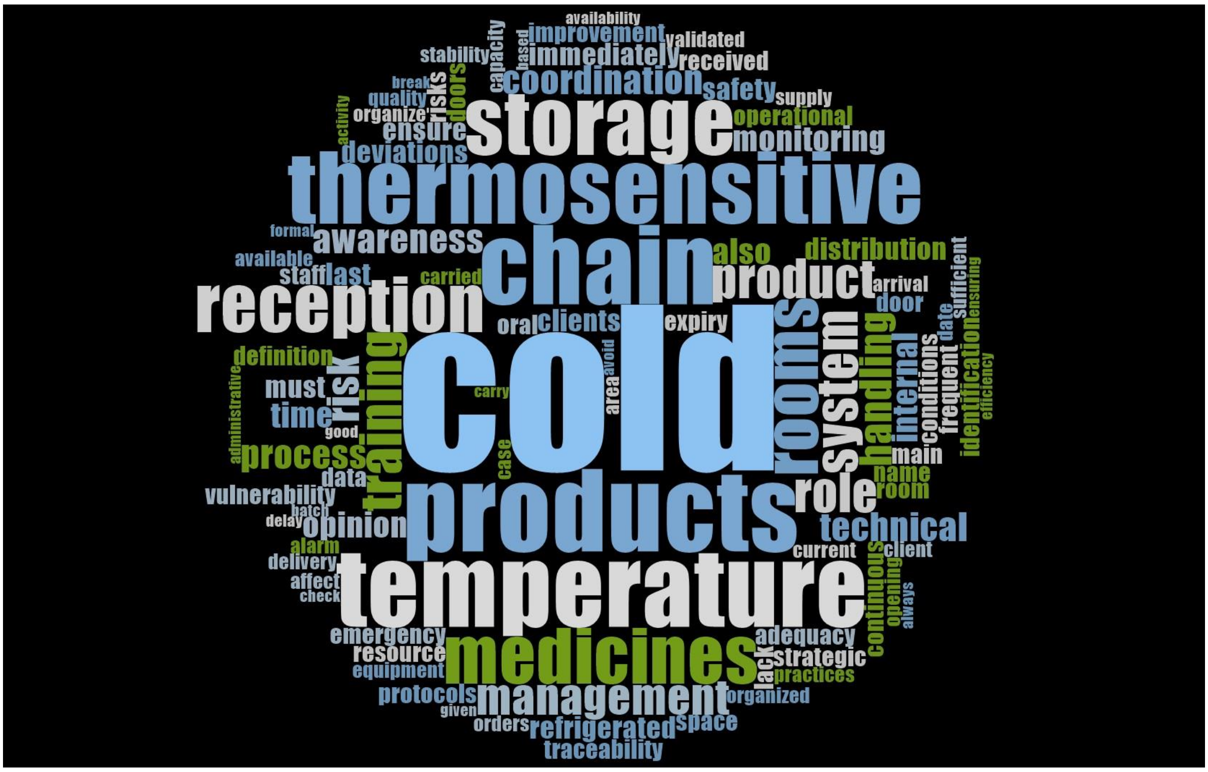
When comparing both phases, a clear operational contradiction appears. Staff members demonstrate strong awareness of the sensitivity of thermo sensitive medicines, yet the logistical system itself remains structurally fragile. Cold chain protection depends largely on constant human vigilance, as the system operates near full capacity and lacks sufficient automated monitoring and infrastructural safeguards.

2. Data Processing and Thematic Synthesis (NVivo)

The qualitative transcripts were analyzed using NVivo software to systematically categorize the logistical vulnerabilities and risk sources identified by the respondents.

An initial exploratory lexical analysis was performed. As shown in the word cloud below, participants' vocabulary centered heavily on terms such as "cold," "temperature," "chain," "products," "storage," "reception," "thermo sensitive," "medicines," and "management." This confirms that maintaining the thermal stability of thermo sensitive medicines is the absolute priority in cold chain management for the staff.

Figure 4: Word cloud of interview terms



Source: NVivo output.

Following this step, the data was coded into specific thematic nodes to identify and prioritize the root causes threatening the cold chain. The synthesized results are presented in the hierarchical table below.

Figure 5: Hierarchy of thematic nodes and frequencies of identified operational vulnerabilities

Nœuds

Nom	Sources	Références
organizational and operational vulnerabilities	5	21
lack of space and overstocking	4	10
frequent door opening	3	6
processing delays	2	2
lack of coordination and staff	2	3
technical and material vulnerabilities	4	9
lack of monitoring and cooling equipment	4	6
breakdowns and power outages	2	2
weak insulation	1	1
human vulnerabilities	4	8
lack of awareness and training	4	6
handling and transfer errors	2	2
transport related vulnerabilities	1	3
temperature deviations during transit	1	3

Source: NVivo output.

Based on the NVivo thematic coding, the foundational causes of thermal deviations at the PCH Annaba Annex can be grouped into four interconnected categories:

The most critical challenges are organizational and operational factors (21 references). The data shows a dangerous chain reaction: chronic lack of space and severe overstocking force staff to constantly move products during reception and storage. This congestion leads directly to frequent and prolonged opening of cold room doors, which is the primary trigger for internal temperature disruptions.

This operational strain is further worsened by technical and material vulnerabilities (nine references). Although the PCH has monitoring equipment, staff expressed serious concerns about its insufficiency such as the inconsistent availability of data loggers during reception or in transit trucks and limited cooling capacity.Thermosensitive medicines are very much exposed to these deficiencies during mechanical breakdown or power outage due to overstocking cold rooms.

These daily pressures are compounded by human factors (Eight references). The interviews revealed a significant lack of ongoing training and risk awareness. When staff are forced to work quickly in congested areas during unloading and transfer, the likelihood of handling errors a major source of physical risk increases dramatically.

Finally, transport-related vulnerabilities, such as poor insulation causing temperature deviations during upstream transit, were the least mentioned by internal participants (3 references). This reflects the PCH's distribution model, in which downstream transportation is usually handled by clients using their own insulated boxes or trucks. As a result, these variables fall largely outside the daily observation of warehouse personnel.

3. Assessment of Current Practices and Risk Management Maturity

The PCH Annaba Annex initiated the ISO 9001:2015 certification process in 2018. While this effort produced a formal macro-level risk map, it does not fully capture the micro-logistical and daily pressures currently faced by the warehouse.

To measure the gap between this formal institutional framework and operational reality, an assessment grid was developed based on field observations and semi-structured interviews. This grid evaluates the actual maturity of the risk management process according to the four fundamental steps of the ISO 31000 standard.

Table VII: Observation Grid of the Risk Management Process (PCH Annaba Annex)

Risk Management Phase	Field Assessment	Operational Observations
Risk Identification	**Limited (Theoretical Focus)**	Official maps focus on major macro-threats (e.g., total cooling unit failure or general product deterioration). In contrast, hidden daily logistical vulnerabilities (e.g., frequent door openings and congestion) are largely ignored in formal documentation.
Risk Evaluation & Prioritization	**Not Applied Operationally**	Despite official severity scales (1 to 4), daily tasks follow an "emergency logic." Priority is given to rapid truck unloading rather than systematic assessment of thermal risks for each operation.
Risk Treatment	**Reactive**	Preventive measures such as alarms exist, but interventions are mainly reactive following malfunctions rather than addressing root organizational causes .

Monitoring & Review	**Absent**	There is no institutionalized feedback system to learn from minor thermal deviations or handling errors in order to update procedures and train personnel.

Source: Developed by personal efforts.

Beyond the structured phases of the ISO 31000 standard, the qualitative field diagnosis revealed five critical operational deficiencies regarding the day-to-day management of the cold chain:

- **Documentation and Standard Operating Procedures (SOPs):** Daily operations depend on the hidden knowledge which experienced staff members possess instead of following established procedures. The organization faces significant risk because essential personnel can become unavailable or leave the company.
- **Risk Culture and Awareness:** The organization responds to risks by implementing reactive measures. The organization treats minimal logistical disruptions as common occurrences while it considers risk management to be an administrative burden that hinders its ability to safeguard thermosensitive products.
- **Preventive Maintenance Planning:** The organization does not have a maintenance plan which includes scheduled maintenance for essential cooling systems. The organization responds to equipment failures by waiting until problems occur which results in extended periods of equipment inactivity.
- **Traceability and Anomaly History:** The facility lacks organized records of maintenance activities and documented thermal deviations which forces technicians to rely on their personal recollections. This issue prevents organizations from detecting failure patterns which would enable them to build preventive strategies.
- **Cold Chain Performance Indicators (KPIs):** Management needs real-time monitoring systems which display measurable data about cold chain operations. The absence of metrics creates obstacles for organizations which require data to make decisions while it prevents them from implementing structured methods of continuous improvement.

The assessment results indicate that the PCH Annex does not suffer from a complete absence of risk management, but rather from a distinct “organizational duality.” On paper, the facility has formal tools and an administrative structure aiming for quality compliance. However, at the warehouse level, these tools face daily constraints that make them insufficient for managing precise, micro-logistical vulnerabilities.

Interviews confirmed that employees frequently work under intense pressure from incoming product flows that exceed available storage capacity. This pressure transforms risk management from a proactive and planned process into a reactive and instantaneous one. Instead of relying on the official risk map, workers depend on personal experience to protect thermosensitive medicines during peak periods.

Furthermore, the staff's safety culture is heavily product-centric focused strictly on maintaining the 2°C to 8°C range while often neglecting the logistical process itself (such as optimizing space and minimizing physical handling). This fragmented perspective highlights the urgent need to develop a new operational vulnerability map derived directly from daily activities rather than focusing solely on macro-threats. This empirical mapping will be detailed in the subsequent sections.

4. Risk Assessment

4.1. Risk Identification

In line with the ISO 31000 risk management process, major risks must be formally identified before applying detailed analytical tools. Although the NVivo thematic analysis effectively highlighted the daily operational vulnerabilities (root causes), these need to be linked with the broader macro-level risks facing the PCH Annaba Annex.

Through cross-analysis of the institution's official risk map and empirical field observations, the main threats to the cold chain can be categorized into three major risk profiles:

- First risk (R1) : Deterioration of Thermo sensitive Products.
- Second risk (R2): Loss of Thermal Traceability.
- Third risk (R3) : Total Cold Chain Rupture (Infrastructure Failure).

These three profiles were strategically selected to group multiple operational failures into distinct categories based on their critical impact, ensuring the research remains focused on safeguarding medicine quality, protecting patient health, and maintaining the therapeutic efficacy of the products.

Table VIII: Identification and Description of Major Cold Chain Risks

RISK	Description	Causes	Real Example from Fieldwork	Impacts
R1	Degradation of medicines due to failure to maintain the required temperature range of 2°C to 8°C during daily operations.	• Overstocking and frequent opening of cold room doors. • Handling errors caused by overcrowding and rushing.	During fieldwork, a box of thermo sensitive medicines was accidentally left in the ambient area instead of the cold room. It was returned without checking its temperature, based only on the assumption that the exposure time was short.	• Permanent loss of medicines. • Financial losses for the PCH. • Risk of critical medication shortages for patients.
R2	Inability to prove that the cold chain was continuously maintained, making the medicines legally unusable even if they are physically fine.	• Lack of tools to verify temperature upon arrival before storage in cold rooms. • No temperature monitoring during transport from suppliers.	Trucks arriving from Algiers often had no active data loggers. Reception staff could not verify the temperature during transit and had to place the products directly into the cold rooms.	• Mandatory quarantine of batches. •Administrative delays. • Possible destruction of good medicines due to regulations.
R3	Total loss of temperature control due to complete failure of the cooling system.	• Aging and poorly maintained cooling equipment. • Prolonged power outages. • Failure of the backup generator.	During a long power outage, the backup generator also failed. As a result, the cold rooms were left without any cooling system for several hours.	• Emergency transfer of stock to another cold room. • Major financial losses from destroyed medicines. • Serious disruption to the regional hospital supply chain.

Source: Developed by personal efforts.

4.2. Risk Analysis, Evaluation, and Treatment

Once the major logistical threats have been identified, the next critical phase of the ISO 31000 framework requires a deep diagnostic of their root causes, a mathematical evaluation of their criticality, and the formulation of risk control measures. To achieve this, the following subsections utilize a combination of analytical tools to dissect, score, and ultimately treat the vulnerabilities observed within the facility.

4.2.1. ISHIKAWA

The Ishikawa (or Fishbone) diagram serves as the primary analytical tool for deconstructing the logistical failures observed at the PCH Annaba Annex. Rather than treating a temperature excursion as a singular random event, this method systematically maps the underlying physical, human, and procedural variables that trigger the disruption.

To ensure strict methodological transparency, the qualitative data extracted from the NVivo thematic analysis was systematically categorized into the 6M framework (Manpower, Methods, Machine, Material, Milieu, and Measurement).

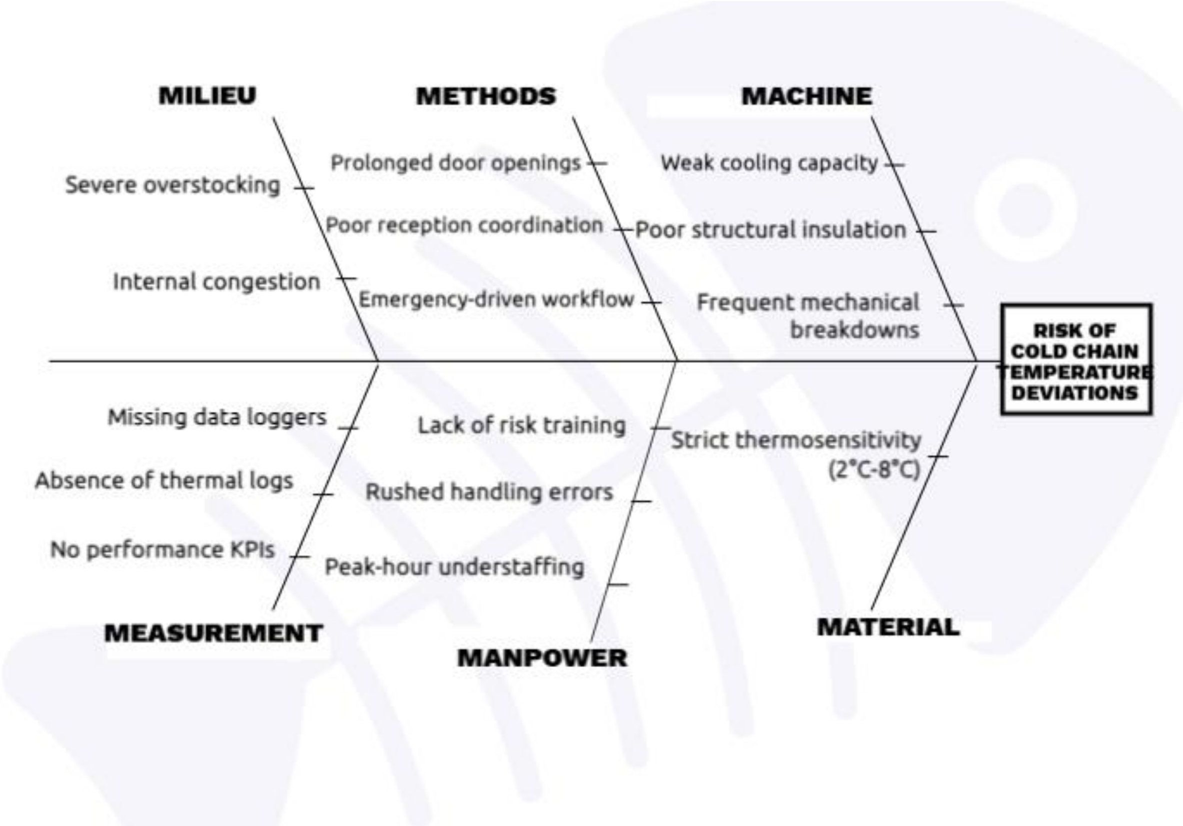
Table IX: Mapping of NVivo Operational Vulnerabilities to the 6M Categories

6M Category	Identified Root Causes
Milieu (Infrastructure & Environment)	• Chronic lack of space and severe overstocking within the facility. • Internal congestion forcing constant movement of products.
Methods (Procedures & Organization)	• Frequent and prolonged opening of cold room doors. • Processing delays and lack of coordination during operations. • Tasks governed by an "emergency logic" rather than proactive assessment.
Machine (Equipment & Technology)	• Limited cooling capacity and weak structural insulation. • High vulnerability to mechanical breakdowns and power outages.

Manpower (Human Force)	• Significant lack of ongoing training and risk awareness. • Increased likelihood of handling errors due to rushing in congested areas. • General lack of sufficient personnel during peak unloading.
Material (The Product)	• Strict thermo sensitive nature requiring an absolute 2°C to 8°C range.
Measurement (Traceability & Metrics)	• Inconsistent availability of temperature data loggers during transit. • Complete absence of systematic intervention logs and thermal deviation records. • Lack of real-time performance dashboards (KPIs) to monitor cold chain compliance.

Source: Elaborated by the author based on NVivo thematic analysis (2026).

Figure 6: Ishikawa Diagrame



Source : Developed by personal efforts.

As illustrated in the Ishikawa diagram above, the thermal deviations at the PCH Annaba Annex are the result of a complex, interconnected system failure rather than isolated incidents. The absolute thermal fragility of the medicines establishes a strict baseline of risk.

This risk is severely amplified by spatial and infrastructural congestion, which forces staff into a reactive, emergency-driven workflow. Compounded by structural cooling deficits and a lack of reliable thermal traceability sensors, this high-pressure environment exponentially increases the probability of human handling errors.

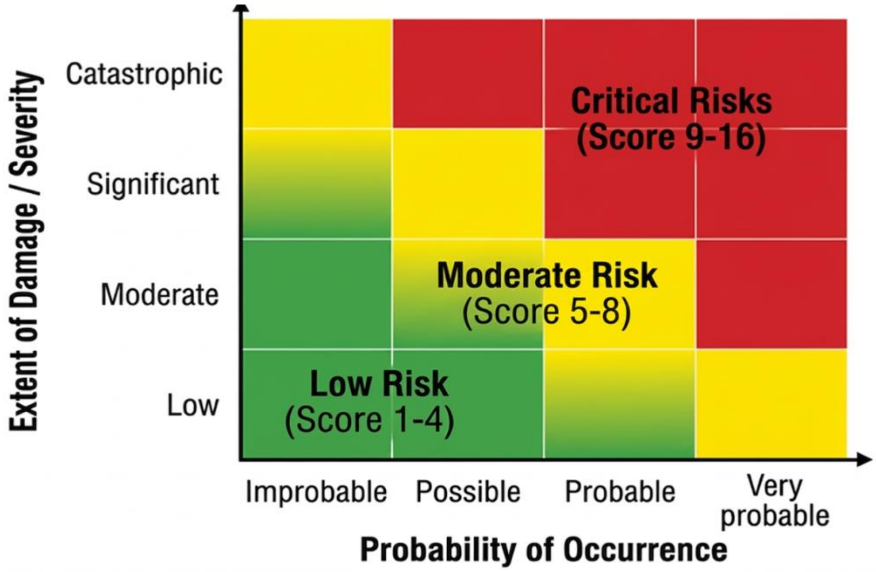
4.2.2. RISK MATRIX

The Risk Matrix is a systematic classification tool used to cross-reference the frequency of occurrence of adverse logistical events with their potential severity. To ensure maximum precision for the PCH Annaba where the absolute priority is the preservation of thermo sensitive medicines a strict 1 to 4 evaluation scale was selected. This even-numbered scale eliminates the "neutral middle ground", forcing a definitive evaluation of the logistical vulnerabilities identified during the field assessment.

The objective is to calculate the Criticality (Criticality = Frequency × Severity) and classify risks to determine intervention priority:

- **Red Zone (Critical Risks - Score 9 to 16):** Unacceptable risks posing a direct threat to the integrity of thermo sensitive medicines. These require immediate Corrective and Preventive Actions (CAPA).
- **Yellow Zone (Moderate Risks - Score 5 to 8):** Significant logistical constraints requiring scheduled mitigation.
- **Green Zone (Low Risks - Score 1 to 4):** Minor anomalies managed through routine continuous improvement.

Figure 7: The 4x4 Risk Matrix



Source: Developed by personal efforts.

The Risk Matrix uses a two-dimensional evaluation framework which employs a fixed scoring system that ranges from 1 to 4. The system measures how often events occur with a frequency scale that goes from 1 (Rare) to 4 (Frequent) and it assesses the impact of events through a severity scale that ranges from 1 (Minor) to 4 (Catastrophic). Each value was discussed with internal experts and operational staff at the PCH Annaba, and then cross-referenced with internal documents and our NVivo thematic analysis to ensure the results reflect the actual field reality.

Table X: Calculation of Risk Criticality and Priority Levels.

RISK	Frequency (1-4)	Severity (1-4)	Criticality (F × S)	Priority Level
R1	2	4	8	Moderate
R2	4	4	16	Critical
R3	1	4	4	Low

Source: Developed by personal efforts.

The Risk Matrix establishes the mathematical rules for the facility's vulnerabilities. R2 (Traceability Loss) is the only critical priority (scoring 16), demanding immediate daily intervention. R1 (Product Deterioration) is classified as a moderate risk (scoring 8), requiring continuous monitoring. Finally, R3 (Infrastructure Failure) is a low risk (scoring 4), requiring standard, scheduled prevention.

4.2.3. FMEA

The Failure Mode, Effects, and Criticality Analysis is a methodical approach that allows for the identification, evaluation, and classification of potential process failures by assigning a criticality index to each risk. This tool is commonly used in the pharmaceutical sector to anticipate problems that could affect the quality of thermosensitive products, patient safety, or operational continuity.

In the context of this research, the FMEA represents the quantitative extension of our qualitative diagnosis. It was used to evaluate and classify the risks identified across the entire cold chain of the PCH Annaba Annex, in order to direct mitigation efforts toward the most critical vulnerabilities.

Objectives of the FMEA within the study:

- To impartially evaluate the operational risks identified during the field study.
- To assign a strict score to each risk based on three criteria evaluated on a scale of 1 to 4:

- Gravity (G): The potential impact of the risk on drug integrity.
- Occurrence (O) The probability or recurrence of the risk occurring.
- Detectability (D): The capacity of the current system to identify the risk before it creates a disruption.

- To calculate the criticality level (G × O × D)

The scoring was rigorously established based on:

- Testimonies from internal experts and operational staff, structured by the NVivo thematic analysis.
- The review of the PCH risk mapping.(Appendix L)

To evaluate the identified operational risks, a multi-criteria scoring grid was developed and validated before its integration into the research protocol. This grid provides a four-level rating system for the three parameters of the AMDEC method: Gravity (G), Occurrence (O), and Detectability (D).

Table XI: Operational Risk Evaluation Grid according to the AMDEC Method

Scale	Risk Assessment Criteria		
	Gravity (G)	Occurrence (O)	Detectability (D)
4	**Major:** Total shutdown or irreversible damage to the process.	Frequent	**Undetectable:** No control measures exist; extremely difficult to identify.
3	**Moderate:** Notable disruption of the operating chain.	Probable	**Difficult:** Uncertain or late detection.
2	**Minor**: Limited impact; correction possible without shutdown.	Rare	**Possible:** Probable detection via regular manual checks.
1	**Acceptable:** Negligible effect without operational consequences.	Very Rare	**Obvious:** Risk is easily detectable by the system.

Source: Developed by personal efforts.

This table presents a four-level scoring system applied to the three parameters retained for this analysis: the Gravity (G) of the consequences on the pharmaceutical process, the Occurrence (O) of the failure, and the Detectability (D) of the risk before it occurs.

These three dimensions combined allow for a rigorous prioritization of the identified operational risks based on their criticality level. This hierarchy serves to guide the definition of appropriate CAPA, ultimately aiming to improve the reliability, safety, and overall performance of the PCH Annaba cold chain.

Tableau XII: Risk Criticality Intervals based on FMEA Criteria (Scale 1-4)

Criticality Interval (C)	**Occurrence (O)**	**Gravity (G)**	**Detectability (D)**	**Justification**
(1 - 8)	(1 - 2)	(1 - 2)	(1 - 2)	Low-range combinations between 1^3 and 2^3
(9 - 18)	(2 - 3)	(2 - 3)	(2 - 3)	Mid-range values 2^3

				exceeding the threshold.
(19 - 35)	(2 - 3)	(2 - 3)	(2 - 3)	High-range values centered around the 3^3 (27) threshold.
(36 - 64)	(3 - 4)	(3 - 4)	(3 - 4)	Critical-range values reaching the absolute ceiling of 4^3

Source: Developed by personal efforts.

The following scale translates the calculated criticality scores (C) into specific management priorities. These thresholds determine the level of acceptability for each logistical failure and dictate the urgency of the required corrective actions within the PCH Annaba cold chain.

Tableau XIII: Risk Priority and Acceptability Scale

Evaluated Risk Level (C)	Default (Criticality)	Acceptability and Required Actions
$1 \leq C \leq 8$	Acceptable	Acceptable without any additional measures. The risk is controlled.
$9 \leq C \leq 18$	Moderate	Acceptable with current control measures.
$19 \leq C \leq 35$	Undesirable	Unacceptable : requires medium-term risk management measures.
$36 \leq C \leq 64$	Unacceptable	Unacceptable: requires urgent and immediate risk control measures.

Source : Developed by personal efforts.

The table below presents the FMEA matrix results, established through the triangulation of field expertise, internal PCH records, and our NVivo thematic analysis to ensure operational accuracy.

Tableau XIV:FMEA Table

Critical Asset	Asset Function	Risk	G	O	D	C	Action Plan
Refrigerated Vehicles & Reception Dock	Maintain and verify thermosensitive medicines strictly between +2°C and +8°C during transport and arrival.	**R2**	**4**	**4**	**4**	**64**	Impose systematic temperature verification at the reception dock, and equip delivery vehicles with portable data loggers integrated with immediate (audio and visual) alarms to alert the driver.
Cold Rooms & Refrigerated Vehicles	Maintain thermosensitive medicines strictly between +2°C and +8°C during storage and distribution.	**R1**	**4**	**2**	**2**	**16**	Enforce strict isothermal packing protocols, minimize door-opening durations, and conduct routine temperature mapping.
Electrical Grid & Backup Generators	Provide uninterrupted electrical power to all refrigeration infrastructure at the regional annex.	**R3**	**4**	**1**	**1**	**4**	Install an automatic transfer switch (ATS) for instant generator activation and conduct mandatory monthly stress (load) tests on backup systems.

Source: Developed by personal efforts.

The FMEA analysis ranks the facility's vulnerabilities by their Criticality (C) scores, showing exactly where immediate action is needed. The results show an operational hierarchy that establishes:

- **R2 (Loss of Thermal Traceability):** This is the primary threat, scoring a critical 64. The high score exists because temperature failures during transport become undetectable (D=4). Staff members remain unaware of temperature fluctuations until the medicines enter the cold room. This situation creates an unacceptable interruption in the cold chain.

- **R1 (Product Deterioration):** This risk scored a 16. The situation requires more secure packing and handling protocols because staff members handle products daily which results in temperature deviations that occur with O=2 probability and only D=2 partial detection.

- **R3 (Infrastructure Failure):** This scored the lowest at 4. A total power outage is severe (G=4), but it is very rare (O=1) and instantly noticeable (D=1). The organization can manage this risk through regular maintenance and its automated backup systems.

Identifying these risks is only the first step. The high criticality score of R2 requires a practical and immediate solution. To eliminate the transport blind spot and fully secure the cold chain, the annex must implement a Corrective and Preventive Action (CAPA) plan. The following section outlines the specific equipment and procedures needed to reduce these risks to safe, compliant levels.

4.2.4. CAPA

The Corrective and Preventive Action (CAPA) plan serves as the practical response to the vulnerabilities quantified in the FMEA matrix. The PCH Annaba Annex needs to implement specific structural and operational changes to achieve their goal of decreasing criticality scores. The following strategies address each specific risk profile to restore and maintain complete cold chain integrity.

- **Loss of Thermal Traceability (Critical Priority)**

R2 represents an unacceptable operational gap with a criticality score of 64, driven entirely by the inability to detect temperature failures during the transport phase. The following actions are designed to physically eliminate this transport blind spot:

- **Corrective Action:** The facility must impose systematic temperature verification at the reception dock. The system establishes verification procedures which require thermosensitive medicines to undergo testing immediately after their arrival at the facility and before their transfer to the cold storage areas.

- **Preventive Action:** The facility must equip all delivery vehicles with portable data loggers. The system requires loggers to provide active monitoring through immediate audio and visual alarms which will notify drivers about temperature deviations during transportation.

➢ **Deterioration of Thermosensitive Products (Moderate Priority)**

With a criticality score of 16, R1 is a constant, moderate threat caused by daily handling procedures and structural constraints. The goal of this CAPA is to stabilize the internal environment:

- **Corrective Action:** Management must minimize door-opening durations to reduce internal temperature disruptions caused by overcrowding and rushing. Additionally, the staff must enforce strict isothermal packing protocols to protect the products during physical transfer.

- **Preventive Action:** The facility must conduct routine temperature mapping. This will scientifically verify that the cold rooms and refrigerated vehicles can maintain the medicines strictly between +2°C and +8°C during all storage and distribution phases.

➢ **Total Cold Chain Rupture (Low Priority)**

Although an infrastructure failure scores the lowest criticality (4) due to its rarity and high detectability, the severity of a total power outage requires highly reliable backup mechanisms.

- **Corrective Action:** The regional annex must install an automatic transfer switch (ATS). This ensures instant generator activation to provide uninterrupted electrical power to all refrigeration infrastructure in the event of a grid failure.

- **Preventive Action:** Management must mandate and conduct monthly stress (load) tests on the backup systems. This scheduled, long-term maintenance will guarantee the generators can successfully support the facility's full mechanical load during an emergency.

5. Strategic Recommendations for Risk Mitigation

Addressing the critical failures highlighted by the field observations and the FMEA requires a structured response. The following recommendations provide practical solutions designed to upgrade the PCH Annaba Annex's risk management system, keeping the strict requirements of the pharmaceutical cold chain at the center of every operational improvement.

5.1. Revision of Reception and Storage Procedures

- **Objective:** Reinforce controls upon the arrival of thermosensitive products at the annex to prevent handling errors, avoid temperature excursions, and ensure regulatory compliance.

- **Concrete Proposals:** Draft and update standard operating procedures (SOPs) specifically for the following stages:

    - **Systematic Verification:** Mandatory checking of transit documents and, most importantly, the extraction and verification of temperature data loggers the moment a truck arrives.

    - **Visual Inspection:** Immediate verification of isothermal packaging integrity and product temperature before integration into the cold rooms.

    - **Workflow & Storage Reorganization:** Reorganize the physical storage space applying a strict FEFO method which is mandatory for pharmaceuticals and establish clearly demarcated zones to separate compliant medicines from quarantined batches.

    - **Staff Training:** Train logistical operators (storekeepers and receiving staff) on these new procedures, accompanied by physical checklists used at the unloading dock.

- **Expected Benefits:**

    - Significant reduction of regulatory non-compliance risks during ANPP or internal audits.

- Reduction of product losses and deterioration caused by rushed or incorrect storage.
- Improved coordination between the receiving dock and the responsible pharmacist.

5.2. Establishment of a Risk Tracking Dashboard

- **Objective:** Provide management with a simple and effective monitoring tool to visualize cold chain risks in real-time, track logistical incidents, and facilitate rapid decision-making.
- **Implementation Details:**
    - Develop Key Risk Indicators (KRIs) specifically adapted to the PCH cold chain:
        - **Supply/Transport:** Rate of delayed supplier deliveries, number of transit temperature anomalies detected upon arrival.
        - **Storage Operations:** Average duration of cold room door openings, number of triggered internal temperature alarms.
        - **Logistics:** Average processing time to transfer thermosensitive pallets from the truck into the cold room.
    - Create a centralized dashboard accessible to all department heads via a shared platform (e.g., Google Sheets, Excel on Intranet, or Power BI).
    - Conduct a monthly analysis led by the Operations Department and Quality Control, triggering automated alerts if critical thresholds are crossed (e.g., three consecutive thermal deviations from the same transport provider).
- **Expected Benefits:**
    - Proactive anticipation of logistical bottlenecks rather than reactive crisis management.
    - A global, data-driven vision of operational risks.

  - A solid, documented foundation for internal audits.

5.3. Enhancement of Staff Training and Awareness

- **Objective:** Minimize human errors during peak handling times and replace the current "emergency logic" with a proactive culture of quality and risk prevention among warehouse teams.

- **Implementation Details:**

  - Establish mandatory, specialized training sessions for all logistical actors (receivers, storekeepers, drivers) focusing strictly on the sensitivity of cold chain products (+2°C to +8°C).

  - Display visual aids and clear internal notifications (posters near cold room doors) to constantly remind staff of best practices (e.g., minimizing door openings, correct isothermal packing).

- **Expected Benefits:**

  - Drastic decrease in internal thermal shocks caused by human handling errors.

  - Increased staff engagement in a sustainable quality and performance approach.

  - Better reactivity and adherence to protocols during critical situations (e.g., power outages).

5.4. Implementation of an Annual FMEA Program

- **Objective:** Transform risk management from a one-time academic exercise into a continuous cycle of risk identification and control.

- **Implementation Details:**

  - Organize annual FMEA workshops involving multiple key departments (Logistics, Technical/Maintenance, and the Pharmacist).

  - Re-evaluate the Gravity (G), Occurrence (O), and Detectability (D) scores of the facility's assets based on the events and data collected over the previous year.

- **Expected Benefits:**
  - Continuous prevention of emerging logistical risks.
  - Documented continuous improvement that adapts to changes in the annex's infrastructure or supply volumes.
  - Strengthened inter-departmental cooperation regarding cold chain security.

5.5. Formalization of a Quality-Logistics Document Repository (SOPs)

- **Objective:** Standardize, centralize, and secure the essential logistical processes of the cold chain, officially transitioning the annex away from informal, experience-based habits toward a highly regulated operational framework.

- **Implementation Details:**
  - **Centralization of Documentation:** Implement a secure digital platform (such as a shared Intranet portal or Electronic Document Management system) to centralize all essential supply chain and quality documents, making them universally accessible to the Pharmacy, Logistics, and Technical departments.
  - **Drafting Standard Operating Procedures (SOPs):** Formalize and validate written procedures for the most critical logistical nodes, specifically: off-hours reception of thermosensitive medicines, FEFO stock rotation protocols, active temperature monitoring rules, and emergency response workflows for cooling unit failures.
  - **Version Control and Archiving:** Establish a strict versioning and approval process to ensure that storekeepers and technicians are always operating according to the most recent, compliant handling protocols. This must include the archiving of daily temperature logs and maintenance records.

- **Expected Benefits:**
    - **Operational Continuity:** Guarantees that the cold chain remains secure and processes remain consistent even in the event of key personnel absences or high staff turnover.
    - **Audit Readiness:** Drastically simplifies internal and external regulatory inspections (such as ANPP audits) by providing immediate, organized access to compliant procedures and historical thermal data.
    - **Reduction of Human Error:** Eliminates ambiguity in the handling of thermosensitive products by providing clear, written instructions rather than relying on verbal communication during peak rush hours.

Section 02: Results Discussion

The field diagnosis conducted at the PCH Annaba Annex reveals a major logistical challenge: the gap between knowing cold chain requirements in theory and struggling to apply them in a highly vulnerable physical environment. This is not just a technical oversight; it is the main symptom of a regional public health organization managing its distribution network based on informal experience rather than structured, proactive data. This discussion moves beyond a simple reading of the Failure Mode and Effects Analysis (FMEA) and the NVivo interview results to offer a strategic interpretation of these systemic weaknesses, comparing them directly with the theoretical frameworks from the literature review.

1. The Illusion of Compliance and the Traceability "Blind Spot"

The first major point of analysis concerns the structural reliability of the upstream transport phase and the severe biases in how logistical compliance is measured. The FMEA calculations identified the loss of thermal traceability (Risk 2) as the facility's most critical threat, generating an unacceptable criticality score of 64. This extreme score is driven entirely by a Detectability rating of 4 (undetectable). The field data explains this precisely: the truck driver confirmed that the journey from Algiers to Annaba takes approximately seven hours, yet the trucks are only equipped with a cabin screen and entirely lack alarm systems. More critically, the Receiving Manager confirmed that shipments frequently arrive at night and are unloaded directly by security guards because the responsible technical staff are absent. It is only the following morning that calibration and sorting occur. This reveals a deep structural bias: the Annex evaluates the safety of its medicines based almost entirely on its internal storage conditions, effectively treating the "blind spot" of transportation as compliant by default. Without active, verified transit records upon arrival, the facility cannot definitively prove the cold chain was continuously maintained, creating an unacceptable regulatory gap. This empirical reality directly validates the theoretical assertions of Allen and McKenna (2017), who identified transportation as the most vulnerable stage in the cold chain due to tracking and equipment reliability disruptions. It also confirms the findings of Ahmed et al. (2025) and Aledi et al. (2025), who demonstrated that delivery logistics constitute the most critical point of failure due to operational errors, inadequate monitoring, and delays.

2. The Vicious Cycle of Spatial Congestion and Reactive Handling

The second axis of analysis focuses on how internal infrastructural limits dictate and warp human behavior. The interviews converge on a critical operational bottleneck: despite having three functional cold rooms with capacities of 65 m^3, 65 m^3, and 132 m^3, the Annex lacks a dedicated refrigerated buffer area and frequently faces severe overstocking. To manage this spatial congestion, staff are forced to constantly move products, requiring them to keep cold room doors open for prolonged periods during unloading. When the internal temperature alarm inevitably triggers due to warm air entering, the storekeeper noted that the official corrective action is simply to "stop the unloading process and close the doors... and wait until the temperature goes down again". This reactive strategy proves that operational bottlenecks are treated with temporary workarounds rather than systemic solutions. The lack of space forces staff into rushed, error-prone handling, directly explaining real-world incidents documented during the field study where boxes of thermosensitive medicines were accidentally left in ambient areas. The short-term convenience of working around spatial limits translates directly into a persistent, moderate risk of product deterioration (Risk 1, FMEA Criticality Score 16). This observation perfectly mirrors the findings of Zribi et al. (2019), who demonstrated that cold chain failures in hospital pharmacy settings are heavily driven by operational weaknesses, insufficient infrastructure, and human-related handling errors rather than purely technical mechanical breakdowns. It also aligns with Wen et al. (2019), who identified inadequate storage planning and poor management of delivery logistics as primary risks to cold chain integrity.

3. Informal Risk Management and the Treatment of Symptoms over Root Causes

The qualitative data highlights a severe deficit in formal Quality Risk Management (QRM) maturity across the facility. While the general management of the PCH previously attempted to implement an ISO 9001:2015 Quality Management System, the Technical Assistant Pharmacist confirmed that the project was discontinued and abandoned. Consequently, the facility operates without formal written Standard Operating Procedures (SOPs) dedicated to temperature excursions; staff rely instead on basic reference tables and personal experience to determine if a product should be assigned a new expiry date. Furthermore, no Key Performance Indicators (KPIs) or dashboards are utilized to monitor logistical efficiency, and the last formal risk management training occurred in 2018. In the event of mechanical issues, maintenance is purely reactive, with technicians intervening only when they "notice anything abnormal" during morning visual checks. This reliance on undocumented "hidden knowledge" means the facility consistently treats the symptoms of logistical failures rather than addressing their root causes. Normalizing workarounds—such as relying on individual memory instead of written SOPs or automated tracking—impoverishes the technical memory of the warehouse and guarantees that handling errors will continuously repeat. This empirical diagnosis echoes the exact industry gap identified by Kumar and Jha (2018), who noted that the application of quality risk management in pharmaceutical distribution remains distinctly less developed compared to the manufacturing sector, where tools like FMEA are standard practice.

4. Strategic Asymmetry and the Justification for Foundational Interventions

The final point of analysis emerges from confronting these internal realities with the international literature, revealing a striking asymmetry regarding technological advancement. While recent global literature heavily emphasizes the use of advanced digital tools like Machine Learning, Artificial Intelligence, and Blockchain for predictive risk mitigation and real-time anomaly detection in pharmaceutical supply chains (Chowdhury, 2025; Zhang et al., 2021; Martinez, 2025), the PCH Annaba Annex operates in a distinctly different, more constrained reality. It is critical to note that while the Annex successfully maintains continuous electronic data loggers and four environmental probes inside all three of its cold rooms, this excellent technological control completely stops at the warehouse doors. During the critical transport phase, the supply chain suffers from a severe lack of data loggers in transit trucks. Furthermore, internally, the facility completely lacks an empty backup cold room for emergency product transfers in the event of a total mechanical failure. This asymmetry explicitly justifies the deliberately pragmatic and modest nature of the strategic recommendations formulated for the Annex. In a public sector distribution environment facing foundational spatial constraints and a disconnected transit network, the immediate priority cannot be algorithmic prediction or cloud computing. Rather, as strongly suggested by the operational framework proposed by Mushabaywa et al. (2025), building true operational resilience requires starting with standardized deviation documentation, strict procedural governance (such as systematic FEFO validation and reception checklists), and closing the basic monitoring gaps before attempting any advanced digital integration.

Chapter conclusion

This chapter applied structured risk assessment tools including the Ishikawa diagram, Risk Matrix, and FMEA to expose the critical vulnerabilities within the PCH Annaba cold chain, most notably the transport traceability blind spot and severe spatial congestion. These findings were directly translated into a strategic CAPA plan focused on procedural standardization, continuous thermal monitoring, and proactive risk governance.

Ultimately, this discussion evaluates the PCH Annaba Annex's overall cold chain resilience against international standards and justifies the strategic interventions proposed in our CAPA pla

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GENERAL CONCLUSION

This study aimed to identify and analyze the primary risks associated with the pharmaceutical cold chain, focusing on the Central Pharmacy of Hospitals (PCH) Annaba Annex as a specific case study. Operating within a sensitive and important public health sector, our work sought to structure a risk management system capable of guaranteeing the continuity, quality, and regulatory compliance of temperature-sensitive medicines destined for the Algerian population. Through a qualitative approach combining semi-structured interviews, direct field observation, document analysis, and decision-support tools such as the Ishikawa diagram, Risk Matrix, and FMEA, we aimed to formulate practical operational and theoretical recommendations adapted to the facility's specific challenges.

1. Summary of Essential Results

The NVivo thematic analysis and FMEA calculations revealed two major logistical failures. The most critical threat (Criticality Score: 64) stems from a loss of thermal traceability during the upstream transport phase, while an ongoing moderate risk (Criticality Score: 16) arises from internal spatial congestion and frequent cold room door openings. Although standard equipment like cold room environmental probes are present, the facility's risk governance lacks maturity: the ISO 9001:2015 certification was not renewed, formal Standard Operating Procedures (SOPs) are absent, and monitoring remains strictly reactive rather than proactive. In response to these findings, three priority CAPA strategies were proposed:

- The required implementation of systematic temperature verification at the reception dock and the equipping of all transit trucks with active, portable data loggers.
- The reorganization of physical storage using strict FEFO principles and minimized door-opening durations to reduce the effects of spatial constraints.
- The formalization of a Quality-Logistics Document Repository (SOPs) and a centralized risk dashboard to transition the facility away from informal "hidden knowledge" toward a strictly regulated operational framework.

2. Analysis of Critical Interfaces

During this study, it became clear that cold chain performance depends heavily on the quality of interactions between different operational phases. Two interfaces were particularly critical at the PCH Annaba:

- **The Interface Between External Transport and Internal Reception:** Shipments from Algiers often arrive at night and are unloaded directly by security personnel because the responsible technical staff are absent. The existing protocol for immediate data logger verification at handover is not practically enforced. This operational failure is driven by the frequent absence of data loggers in external transport vehicles (arriving from Algiers) and a lack of trained staff at the reception dock to extract the data. As a result, a critical 'blind spot' occurs. Upon arrival, staff bypass thermal verification entirely and simply organize the medicines into the cold rooms, leaving the transit temperature history completely unknown.(Appendix F)

- **The Interface Between Storage Capacity and Daily Handling:** The structural lack of a dedicated refrigerated buffer area creates major bottlenecks during peak unloading times. Because logisticians cannot stage the products safely, they are forced to keep the main cold room doors open for long periods, directly triggering internal temperature alarms and causing sudden workflow interruptions.

3. Limitations of the Study

This research presents several limitations that must be highlighted:

- The single-case study design focusing solely on the Annaba Annex restricts the direct ability to generalize the specific FMEA risk scores to the other regional hubs (such as Oran, Biskra, Bechar, or Algiers) of the PCH.

- The qualitative sample size, though achieving theoretical saturation internally, excluded the perspectives of external stakeholders, such as independent transport providers or regulatory authorities like the ANPP.

- The absence of historical, quantified Key Performance Indicators (KPIs) regarding past temperature deviations limited our capacity to statistically measure long-term trends prior to our intervention.

4. Answers to the Research Questions

- **Q1. What are the specific internal and external vulnerabilities threatening the preservation of thermosensitive medicines?**

The analysis categorized the vulnerabilities into two distinct environments. Externally, the primary threat is the 'blind spot' of undetected temperature deviations during the 7-hour upstream transit from Algiers. Internally, the facility suffers from human handling errors driven by severe spatial congestion and frequent cold room door openings, alongside the persistent, though controlled, threat of total infrastructure failure, such as power outages.

- **Q2. How can the criticality of these logistical vulnerabilities be rigorously measured and prioritized within a highly constrained public sector environment?**

To effectively evaluate these threats, a mixed-methods approach was required. We utilized NVivo thematic analysis to extract qualitative data from expert interviews, which then fed into an Ishikawa diagram to structure the root causes. Finally, an FMEA matrix was deployed as the quantitative tool to rigorously score and prioritize these vulnerabilities based on their Gravity, Occurrence, and Detectability.

- **Q3. What concrete CAPA can transition the facility to proactive management?**

To transition the facility from a reactive posture to proactive governance, the proposed CAPA plan focuses on immediate operational controls and long-term monitoring. Concrete actions include standardizing reception verification protocols, enforcing the real-time use of data loggers in external delivery vehicles, establishing a centralized KRI dashboard for continuous logistical monitoring, and embedding an annual FMEA review culture among the staff.

5. Avenues for Future Research

To build upon the foundational findings of this initial work, several strategic research avenues should be considered:

- **Extreme Climatic Stress Testing:** Replicate this FMEA framework within PCH annexes located in high-temperature southern regions (such as Béchar and Biskra). Evaluating the pharmaceutical cold chain under severe thermal constraints will test the absolute limits of current logistical resilience and highlight the need for geographically adapted risk management strategies.

- **Cost of Quality (CoQ) and Financial Feasibility:** Future research should translate these logistical criticalities into financial metrics by conducting a Cost-Benefit Analysis (CBA) of the proposed CAPA plan. Quantifying the financial loss of thermally damaged medicines versus the investment required for proactive QMS implementation would provide public decision-makers with a powerful economic rationale for change.

- **Multi-site Comparative Studies:** Broaden the qualitative and quantitative analysis to include all PCH regional annexes across the country. This would facilitate the establishment of a unified, national risk map for public pharmaceutical distribution.

- **Advanced Digital Platforms:** Once a basic, procedurally driven Quality Risk Management (QRM) culture is firmly established, future research should explore the integration of IoT (Internet of Things) sensors and Blockchain technology to enable real-time, tamper-proof thermal tracking across the entire distribution network.

- **Predictive Modeling via Artificial Intelligence:** Develop Machine Learning algorithms capable of anticipating transport delays and thermal anomalies based on historical supply chain and meteorological data, thereby optimizing stock levels and securing transit routes proactively.

To conclude, this thesis demonstrates that an integrated approach combining strict procedural standardization, specific technological upgrades, and the reinforcement of staff training is essential to improve the resilience of the pharmaceutical cold chain. In an era of increasing health security requirements, these recommendations form a strong operational foundation for the PCH Annaba Annex and a realistic starting point for managerial innovation in the public distribution sector.

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Appendix

Appendix A :interview guide (phase 1)

Section	Theme	Questions
General framework and responsibilities	Role and responsibilities	1. Can you present your position and your main responsibilities? 2. What is your specific role in the cold chain of thermosensitive medicines?
Organization of operations	Operational process	3. Can you describe the different stages of the process, from the arrival of the products? 4. What is the average delay between the arrival of the products and their placement in the cold room? 5. Are thermosensitive products handled as a priority? Is there a refrigerated buffer area in case of waiting? 6. How are the products organized in the cold room, and how is the FEFO principle applied? 7. What is the maximum storage capacity to be respected in cold rooms? 8. How are the thermosensitive products organized and processed? 9. How do you organize the planning and management of the flow of thermosensitive medicines between reception, storage, and distribution? 10. How do you ensure daily coordination between the different teams of (reception, warehouse)?
Cold system and technical monitoring	Temperature control system	11. What type of refrigeration system is used in the cold rooms, and does it operate continuously or according to automatic control? 12. How many temperature measuring devices are installed in the cold rooms? 13. Is there an audible, or remote alarm system in case of malfunction or threshold exceedance? 14. Do you use temperature recorders or data loggers? Who is responsible for analyzing the recorded data? 15. Is there a formal procedure for the handling, reading, and use of temperature recorders accompanying thermosensitive products upon receipt? If so, how is it applied in practice? 16. Do you have a real-time monitoring system or continuous electronic temperature recording? 17. Do you check and adjust the sensors regularly to make sure they show the correct temperature?
Storage conditions	Cold storage conditions	18. Can frequent door opening, overloading, or poor insulation affect thermal stability? 19. In your opinion, what are the most sensitive points in storage or in the technical preservation system?

Refrigerated transport	Transport of thermosensitive medicines	20. Can you describe the course of a transport round for thermosensitive medicines, its average duration, and the frequency of stops? 21. Is the refrigerated truck equipped with a continuous temperature control system, an alarm, and a cabin display? 22. What happens in the event of prolonged truck immobilization, traffic jams, breakdowns, or engine shutdown during transport? 23. In your opinion, what are the main risks likely to affect the cold chain during transport?
Risk management	Cold chain risk management	24. Has a formal diagnosis or risk mapping of the risks related to the cold chain already been carried out in the establishment? 25. In your opinion, what are the main sources of risk or malfunction in your activity? 26. What procedure do you apply when an alarm is triggered or when a temperature above 8°C is observed? 27. Is there a formal procedure for managing temperature excursions and a maximum tolerated duration? 28. Are the products placed in quarantine in case of doubt? Who is authorized to decide on the acceptance, rejection, or retention of a batch? 29. Are you often faced with overstock situations of thermosensitive products, and how do you manage them?
Continuity and maintenance	Continuity and maintenance measures	30. Is there a preventive inspection program for the cold rooms, and what is its frequency? 31. What happens in the event of a technical failure, or power outage, and do you have a generator, a backup cold room or an emergency transfer plan to deal with such situations? 32. Is this activity subject to internal audits, external audits, or inspections related to the cold chain? 33. Do you use key performance indicators (KPIs) or a dashboard to monitor the efficiency and safety of the cold chain? 34. Based on your experience, what concrete actions could improve the efficiency and reliability of the current system?
Human factors and continuous improvement	Training and improvement	35. Have you received any training in risk management, quality, or good practices that helps you in managing activities related to the cold chain? 36. In your opinion, what are the main challenges, weaknesses, or limitations of the current system? 37. What improvements could strengthen cold chain safety?

SOURCE : Developed by personal efforts.

AppendixB :Excerpt from the verbatims

Respondent	Function	Question N°	Verbatim Quote
Ms, Souad	**Pharmacist, Technical assistant**	**5**	"Of course. Thermosensitive medicines are given priority during unloading, unlike medicines stored at ambient temperature, because they require special storage conditions. Likewise, when they are taken out, they are handled last in order to preserve their cold temperature. It is also mandatory for every client to bring a cooler to take thermosensitive medicines. However, we do not have a refrigerated buffer area in this branch, although we hope to have one in the future at the Berhal branch."
		24	"The general management of PCH intended to implement a Quality Management System (QMS) in accordance with the requirements of ISO 9001:2015. As part of this initiative, a risk analysis and a risk mapping were carried out, including risks related to the cold chain. However, the Project was discontinued and was not completed."
		25	"In my opinion, the main risks in the cold chain come from temperature deviations during transport, reception, or storage. We also have technical risks, such as refrigeration failures or power outages. Added to that, delays, poor handling, lack of equipment, or insufficient staff awareness can also affect the safety of thermosensitive medicines."
		27	"No, we do not have a formal written procedure specifically dedicated to temperature excursions. However, we use reference tables that indicate two durations for thermosensitive medicines: the first is the maximum time the product can remain out of the refrigerator and still be returned to cold storage without changing its original expiry date; the second is the stability period of the product when it is kept at room temperature, in which case it must not be returned to the refrigerator and a new expiry date must be assigned."
		28	"Yes, of course. We sometimes receive an official notice from CNPN pharmacovigilance or from ANPP instructing us to set a given product aside and not use it, in order to carry out a counter-expertise. If the product is found to be compliant, we

			reintegrate it and unblock it in the system so that it can be distributed to clients. If it is found to be non-compliant, we return it or dispose of it.”
		32	“Yes, this activity was included as part of the internal management review in 2019, including aspects related to the cold chain, but it has not been repeated since then.”
		33	“No, at present we do not use specific key performance indicators or a dashboard to monitor the efficiency and safety of the cold chain.”
		35	“Yes, we received training in 2018 on risk management and quality-related practices that support activities related to the cold chain. However, no further training has been provided since then.”
		37	“In my opinion, cold chain safety could be improved by better control during transport and reception. The temperature must remain between +2°C and +8°C throughout the logistics chain. We already have automatic alarms and monitoring systems in the cold rooms, but the trucks should also be equipped with data loggers and alarm systems. Traceability should be reinforced, and staff should be more aware of good practices.”
MS, Hayette	**Head of Operations Department**	**9**	“The planning is based on an annual distribution program prepared in advance and validated by central management, with monthly averages established to organize supply. Regarding flow management, thermosensitive medicines are first received under controlled temperature conditions, with prior notification to prepare the cold rooms, then immediately stored in refrigerated chambers under continuous temperature monitoring. After storage, distribution is organized according to client requests, ensuring cold chain compliance, and clients are required to use appropriate transport means such as insulated boxes or refrigerated trucks.”
			“There is a strong and well-coordinated collaboration between the reception and storage teams. Upon arrival of the products, the reception team carries out inspection and sorting, then

		10	immediately places thermosensitive medicines into cold rooms. At this stage, a technical reception note is prepared.Afterwards, the storekeeper verifies the products by checking the quantity, expiry date, and batch number. Any discrepancy or missing information is reported immediately, and the technical reception document is then validated and signed. Next, the administrative reception team records the products in the system and issues an administrative receipt. A copy is given to the storekeeper, who attaches it to the technical document and opens a stock record sheet to ensure proper tracking of product movements.”
		34	“Continuous monitoring is essential to ensure the safety of thermosensitive medicines. And to avoid overloading the cold rooms, it is important to have an alternative mobile cold storage unit available. This is necessary because the current cold rooms have limited capacity, which can increase the risk of overcrowding and affect temperature stability.”
MS, **Mouna**	**Responsible for thermosensitive products**	**8**	“Orders for thermosensitive products are organized on a monthly basis. Each client has a predefined schedule allowing them to place one order per month on specific assigned dates. Clients submit their orders according to this planning. On our side, order processing depends on product availability in stock and on strict storage requirements, particularly cold chain conditions. If the products are available, the order is validated and prepared immediately while respecting all conservation conditions. If not, the order is postponed or adjusted based on available quantities, while maintaining close coordination with clients to ensure continuity of supply.”
		29	“Yes, we are often faced with overstock situations. In this case, we carry out an assessment and send it to the central unit to evaluate the possibility of inter-warehouse transfers. We may also, in some situations, rent cold storage rooms. In addition, we contact our clients to check whether they can take part of the medicines concerned.”

Mr, **Faysal**	**Cold Chain Technician**	**11**	"We have positive cold rooms. A positive cold room is a refrigerated storage room whose temperature remains above 0°C. It is designed to store medicines at a chilled but non-freezing temperature, usually between +2°C and +8°C. Its operating system is automatic: when the temperature inside the room rises above the required range, the refrigeration system lowers it again so that it remains within the recommended limits."
		12	"In each cold room, we have one data logger. In addition, each room contains four probes, one in each corner, to measure temperature."
		13	"Yes, there is an audible alarm system with a loud sound that can be heard throughout the company, but it is not a remote alarm system."
		14	"Yes, we use data loggers to record the temperature every minute, and we review this data every day. the person responsible for analyzing this data is Ms. Saida after downloading it into a flash drive from the data loggers."
		16	"Yes, we have both in all the cold rooms. The temperature is displayed continuously and is also recorded electronically for monitoring and review."
		17	"Yes, each cold room undergoes annual calibration and verification, and a specific certificate is issued for each one. In addition, the data loggers are equipped with a system that displays error codes on the screen whenever a problem occurs. Each error code corresponds to a specific issue. For example, if 'Error 6' appears, it means there is a problem with the battery and it needs to be replaced."

		30	"Every morning, I check the cold rooms, monitor their condition, and look for any signs that could lead to future problems. If I notice anything abnormal, I deal with it immediately."
		31	"In the event of a technical failure, we intervene immediately to solve the problem. It may be an electrical fault, for example when a power surge damages a component, or a mechanical fault such as a gas leak. If the repair takes a long time, we transfer the medicines to another cold room but we dont have an ampty backup cold room. In the event of a power outage, we have two generators that start automatically."
Mr, Mohamed	**Storekeeper**	**6**	"We organize the medicines inside the cold rooms according to the type of medicine and the batch number. We apply the FEFO principle by placing the medicines that are closest to their expiry date at the front, near the door, so that they can be easily identified and removed for delivery to the client, and to avoid the expiry of any product inside the storage area."
		7	"We have three cold rooms. The first and the second each have a capacity of 65 m³, while the third has a capacity of 132 m³."
		18	"Yes, it definitely affects temperature stability. When the door is opened frequently, warm air enters. Overstocking also disrupts air circulation, and weak insulation can allow outside heat to affect the cold room."
		19	"In my opinion, the most sensitive point in storage is frequent door opening, because it can disturb the temperature inside the cold room. As for the

			technical preservation system, the most sensitive point is a power outage, because it can stop the refrigeration system.”
		26	“When an alarm is triggered, the first thing we do is stop it so that it does not get damaged. We immediately stop the unloading process and close the doors, because this is usually the main cause, as the cold rooms maintain the required temperature unless warmer outside air enters. We then wait until the temperature goes down again before resuming our work.”
Mr. Samir	Receiving Manager	**3**	“After the arrival of thermosensitive medicines from Algiers, which usually arrive at night in refrigerated trucks, the security agents unload them directly into the cold rooms because the responsible staff are not present at that time. On the following morning, we, as the responsible staff, carry out the sorting and calibration process, compare the delivery note with what was actually received, and then issue a goods receipt note.”
		4	“It varies depending on the merchandise received. The larger the shipment, the longer the delay. However, we make sure that the products are handled and stored as quickly as possible.”
		15	“Yes, there is a formal procedure. However, in practice, temperature recorders are not always sent with the trucks coming from Algiers, so at our annex we do not handle them directly. From what I have seen in Algiers, when recorders are provided, they are collected at the time of receipt, stopped, and their details are recorded. The data are then read and analyzed to verify whether the required transport conditions were respected. If a temperature deviation is detected, the relevant departments are informed, the product may be

			blocked in the information system, and a non-conformity notice is issued to determine the appropriate action, including acceptance, rejection, or disposal.”
		36	“Among the weaknesses of the current system, first, there is a lack of resources and equipment. The cold rooms are not sufficient and are sometimes too small, which leads to overstocking. We do not have a dedicated refrigerated waiting area for sorting the medicines, and the temperature data loggers are insufficient and not always available. Also, there is a shortage of staff in reception.”
Anonymous Interviewee	**Refrigerate Truck Driver (From Algiers)**	**20**	“We give very high importance to the transport of thermosensitive medicines; we cannot take any risks with the cold chain. As soon as we are informed that there are cold products to transport, we start the engine 15 minutes in advance so that the truck can cool down and reach a temperature between 2°C and 8°C. Before that, we clean it thoroughly. The trip from PCH Algiers to the Annaba branch takes about 7 hours. We do not stop frequently, only once or twice at most, for 10 to 20 minutes maximum.”
		21	“Yes, the refrigerated truck is equipped with a system that continuously displays the temperature inside the vehicle, and there is also a screen in the cabin, but there is no alarm system.”
		22	“In the event of a prolonged stop or a traffic jam, we do our best to keep the refrigeration system running and avoid switching off the engine, so that the temperature remains stable inside the truck. In the event of a breakdown, we immediately inform the person in charge and act quickly to protect the

			thermosensitive medicines.”
		23	“In my opinion, the main risks that may affect the cold chain during transport are the long travel time, traffic congestion, any breakdown in the refrigeration system or in the truck itself, poor truck cleanliness, and the driver’s lack of awareness. Frequent stops or unnecessary door opening can also cause temperature changes inside the truck, which may affect the safety of thermosensitive medicines.”

SOURCE: Developed by personal efforts.

Appendix C :Cold Chain Evaluation Interview Questionnaire (phase 2)

Full Name: ______________________
Job Title: _____________________________
Date: _________________________________

Thank you for taking a few minutes to answer these questions regarding your daily experience with heat-sensitive medicines. Your responses will help us evaluate and improve the security of the supply chain.

Theme 1: Daily Operations and Coordination1. Role Definition:

- Briefly, what is your specific role in handling, monitoring, or managing heat-sensitive medications?
- Operational Process: What are the most critical steps you follow in your daily work to ensure the maintenance of the cold chain?
- Internal Coordination: How do you coordinate with other departments (such as receiving, storage, or shipping) to ensure that products are transferred safely without temperature loss?

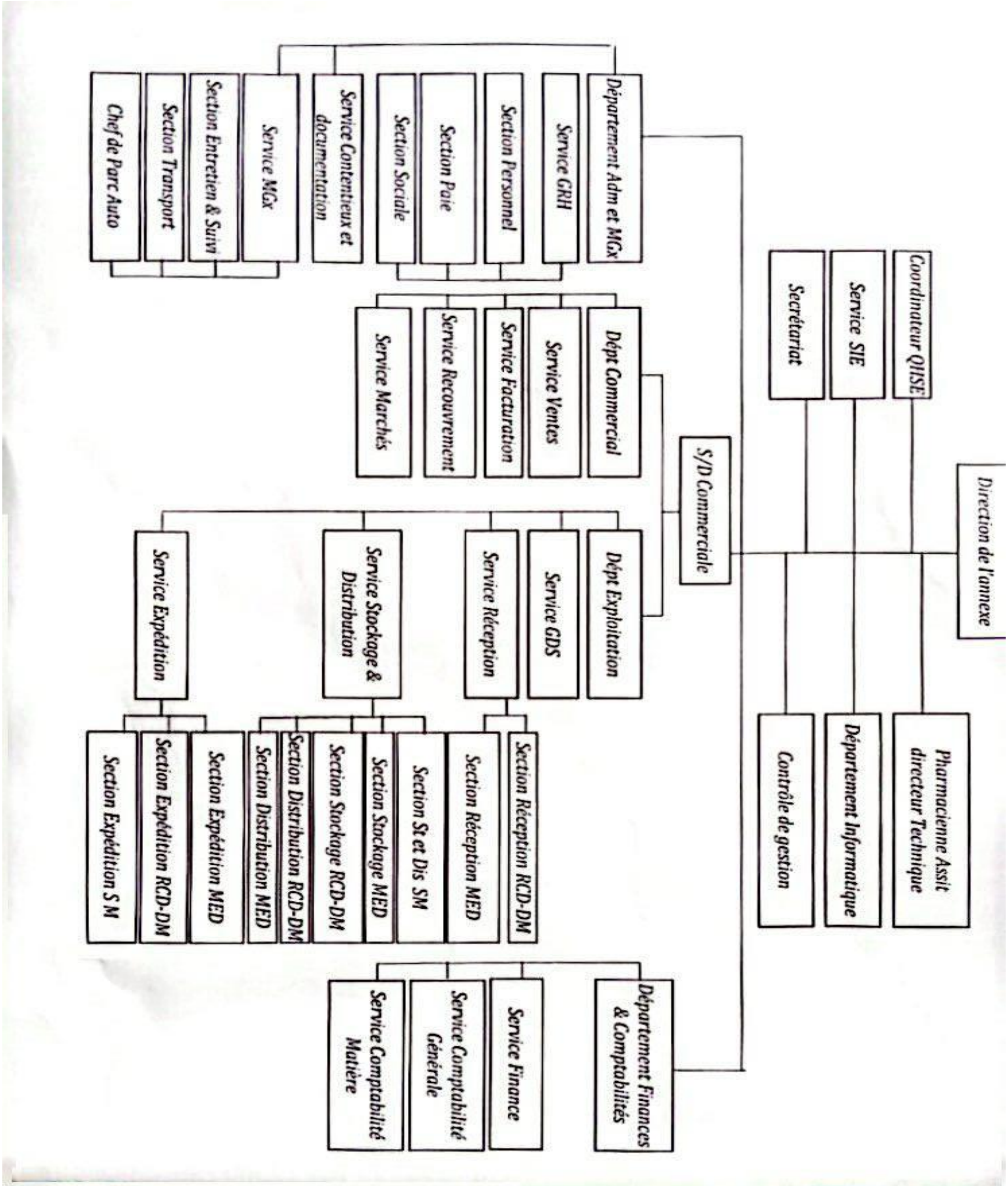
Theme 2: Risk and Emergency Management

- Identification of Vulnerabilities: In your specific workspace, what do you believe is the greatest daily risk to temperature stability (e.g., door openings, delays, lack of space, etc.)?
- Emergency Protocols: If an unexpected event occurs in your area—such as an alarm, power outage, or refrigeration failure—what immediate actions do you take?
- . Deviation Management: If you suspect or are informed that a product has been exposed to a temperature above 8°C, what is your standard procedure for handling this product?

Theme 3: Resources and System Evaluation

- Adequacy of Resources: Do you feel you have the necessary material resources (sufficient cold room space, functional equipment, data loggers) to perform your job safely? If not, what is missing?
- Training and Awareness: In your opinion, is the current level of staff training and awareness regarding cold chain risks sufficient, or does it require reinforcement?
- Strategic Improvement: If you could suggest to the PCH management a single practical improvement or organizational change to improve the reliability of the cold chain, what would it be?

Appendix D: PCH Organizational Structure



Source: Internal document of PCH

Appendix E : Cold Rooms Characterization and Metrology Report

CALTEST MÉTROLOGIE

Inspection-Etalonnage-Vérification des instruments de mesure et contrôle technique
Laboratoire d'étalonnage suivant ISO/IEC 17025:2017
Grandeurs : Dimensionnelle-Température/Humidité-Electricité-Volume /Débit-Pression-Masse/Balance

RAPPORT D'ESSAI
N° T10.01.10.25

DELIVRÉ A:	PHARMACIE CENTRALE DES HOPITAUX (PCH)		
	Annaba		
ÉQUIPEMENT CARACTÉRISÉ:			
Désignation:	Chambre Froide		
Constructeur:	PEGO	N° de série:	2010027898
Modèle:	Datalogger PlusR 200 expert	Identification:	Chambre N°02
Ce certificat comprend 04 pages		Date d'émission:	14/10/2025

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EN/PT/53 Rev 00.0

CALTEST MÉTROLOGIE

Inspection-Etalonnage-Vérification des instruments de mesure et contrôle technique
Laboratoire d'étalonnage suivant ISO/IEC 17025:2017
Grandeurs : Dimensionnelle-Température/Humidité-Electricité-Volume /Débit-Pression-Masse/Balance

RAPPORT D'ESSAI
N° T10.03.10.25

DELIVRÉ A:	PHARMACIE CENTRALE DES HOPITAUX (PCH)		
	Annaba		
ÉQUIPEMENT CARACTÉRISÉ:			
Désignation:	Chambre Froide		
Constructeur:	PEGO	N° de série:	2016027906
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EN/PT/53 Rev 00.07

CALTEST MÉTROLOGIE

Inspection-Etalonnage-Vérification des instruments de mesure et contrôle technique
Laboratoire d'étalonnage suivant ISO/IEC 17025:2017
Grandeurs : Dimensionnelle-Température/Humidité-Electricité-Volume /Débit-Pression-Masse/Balance

RAPPORT D'ESSAI
N° T10.02.10.25

DELIVRÉ A:	PHARMACIE CENTRALE DES HOPITAUX (PCH)		
	Annaba		
ÉQUIPEMENT CARACTÉRISÉ:			
Désignation:	Chambre Froide		
Constructeur:	PEGO	N° de série:	2010027898
Modèle:	Datalogger PlusR 200 expert	Identification:	Chambre N°01
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Source : Internal document of PCH

Appendix F: Procedure for Handling Temperature Loggers for Thermosensitive Products

Pharmacie Centrale des Hôpitaux الصيدلية المركزية للمستشفيات	FORMULAIRE D'ENREGISTREMENT	Référence : INS-TRG -02
	Manipulation des enregistreurs de température accompagnants les produits thermosensibles	Version : 00
		Date d'application : 28-01-2019
		Page : 1 sur 2

1-But et objet :

S'assurer du respect des conditions de transport requises, pour les produits pharmaceutiques et dispositifs médicaux thermosensibles.

2-Domaine d'application :

La présente instruction s'applique à tous les produits pharmaceutiques et dispositifs médicaux importés par la PCH, nécessitant des conditions de conservations particulières.

3-Mots clés/Abréviations :

PDT	Pharmacien directeur technique
CDF	Chaine de froid
PP	Produits pharmaceutiques
DM	Dispositifs médicaux
LNCPP	Laboratoire de contrôle des Produits Pharmaceutiques
ANS	Agence Nationale du Sang

4-Responsabilités :

- Le Pharmacien Directeur Technique veille à l'application de la présente instruction ;
- Le personnel de la DTR-S/D Contrôle et Assurance Qualité est responsable de la manipulation des enregistreurs de température selon les modalités de la présente instruction ;

5 Références :

- Conditions d'exercice de l'activité de distribution des produits pharmaceutiques en gros
- Cahier des conditions techniques à l'importation des produits pharmaceutiques

6-Procédure :

1) Prélèvement :

A. Prélèvement des enregistreurs de température accompagnant les produits thermosensibles à leurs réception et procéder à leurs arrêts.
B. Renseignement de la fiche des enregistreurs de température par l'agent de prélèvement (Nombre d'enregistreurs de température, leurs emplacements (Externe et Interne), Heure d'arrêt, les N° de coli, N° de palette, Référence de l'enregistreur, état de l'enregistreur, Date et heure de réception, DCI-Forme-dosage, Lot N°).

Pharmacie Centrale des Hôpitaux الصيدلية المركزية للمستشفيات	FORMULAIRE D'ENREGISTREMENT	Référence : INS-TRG -02
	Manipulation des enregistreurs de température accompagnants les produits thermosensibles	Version : 00
		Date d'application : 28-01-2019
		Page : 2 sur 2

2) Lecture et exploitation des enregistreurs

A. Lecture des enregistreurs de température (quant elle est possible) et exploitation des données ainsi que leurs transmissions aux fournisseurs.

Si une déviation de température est constatée :
Saisir les directions concernées par courrier (FOR-TRG-09) :

-Direction de stockage et de la distribution :
Afin de positionner le produit lors de la déviation et son emplacement au moment de la déviation
Lettre de réserve au dernier transporteur de la marchandise
Police d'Assurance.

-Direction des Achats (Médicaments – Dispositifs Médicaux et réactifs chimique et dentaire) :
Afin de situer les responsabilités(Incoterm).
Statuer sur le transfert des propriétés.
} Pour une éventuelle réexportation ou incinération.

-Direction des finances et comptabilités :
Afin de surseoir au paiement

-Direction commerciale :
A titre d'information

B. Si la lecture et l'exploitation des enregistreurs de température n'est pas possible, ces derniers sont remis aux représentants des fournisseurs avec décharge.
C. Attente de la notification de respect des conditions de conservation durant le transport

3) Notification du respect des conditions de conservation durant le transport par le fournisseur :

A. Respect des conditions de conservation durant transport

Transmission de la notification à la Direction de stockage et de la distribution

B. Non respect des conditions de conservation durant transport

-Une Notification de la non-conformité du produit sera transmise aux directions concernées : (Directions des achats, direction de stockage et distribution, direction des finances et comptabilité. Direction commerciale. Annexes régionales).
-Blocage du produit sur système informatique.
-Transfert du produit au rebus.
-Transmission d'une copie du dossier à la sous direction affaires réglementaire chargée de la gestion des rebuts (Dossier du lot, notification du fournisseur, courbes de température).

7-Diffusion :

L'original de cette instruction est géré par la direction Technico-réglementaire, deux copies seront diffusées aux : -Directeur général ;
-Cellule d'audit DTR

Source : Internal document of PCH

Appendix G : Batch Release Authorization (ANPP)

الجمهورية الجزائرية الديمقراطية الشعبية

REPUBLIQUE ALGERIENNE DEMOCRATIQUE ET POPULAIRE

وزارة الصناعة الصيدلانية

MINISTERE DE L'INDUSTRIE PHARMACEUTIQUE

AGENCE NATIONALE DES PRODUITS PHARMACEUTIQUES
A.N.P.P

الوكالة الوطنية للمواد الصيدلانية
و.و.م.ص

MIPH/ANPP/DCE/RSC/00116

Alger le 05 FEV. 2026

A l'attention du Pharmacien Directeur

Technique de La Pharmacie Centrale des Hôpitaux

Objet: A/S – KINERET 100mg/0.67ml (Anakinra). Solution injectable en seringue préremplie à 100mg/0.67ml. B/07.

- N° lot : 4356901A
- Fabricant : HOSPIRA ZAGREB (Croatie), pour le compte de SWEDISH ORPHAN BIOVITRUM AB (Suède).

Madame, Monsieur,

Il est porté à votre attention que le lot du produit cité en objet est libéré sous toute réserve, dans les limites du cadre réglementaire ci-après, le respect continu des exigences réglementaires en vigueur, notamment, les conditions de conservation du produit fini lors du stockage et de distribution :

- Les dispositions de la Loi n° 18-11 du 18 Chaoual 1439 correspondant au 2 juillet 2018, modifiée et complétée, relative à la santé, notamment l'article 205 ;
- Vu la classe pharmacothérapeutique « Immunosuppresseurs, inhibiteurs de l'interleukine », et son indication, notamment, le traitement des signes et symptômes de la PR en association avec le méthotrexate, chez les adultes dont la réponse au méthotrexate seul n'est pas satisfaisante ;
- Les dispositions de l'arrêté du 2 Rajab 1442 correspondant au 14 février 2021, fixant le cahier des conditions techniques à l'importation des produits pharmaceutiques et des dispositifs médicaux à usage de la médecine humaine, notamment l'article 6 ;
- Conformément aux dispositions de la décision n° 013 du 30 janvier 2025 portant autorisation temporaire d'utilisation des médicaments non enregistrés inscrits sur la liste établie par le ministère de la santé et destinés à être importés et commercialisés par la pharmacie centrale des hôpitaux au profit des établissements de santé « Anakinra sol inj 100mg»;

Direction des Services de Laboratoires et de la Recherche Pharmaceutique

Direction du Contrôle et de l'Expertise

Lot [illegible] Petit Staouéli (site du Nouvel Institut Pasteur) Dely Ibrahim, Alger-Algérie
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Source : Internal document of PCH

Appendix H : Health, Safety, and Environment (HSE) Policy

Pharmacie Centrale des Hôpitaux	**POLITIQUE**	**Référence : E. PTHSE-GOV-01**
	Health, Safety, and Environment (HSE POLICY)	**Version : 02**
		Date d'application : 03/11/2024
		Page : 1 sur 1

The Directorate General of the Hospitals' Central Pharmacy confirms its desire to make Health, Safety, and Environment one of its priorities, and to make its performance in this area a criteria of progress, and an asset as well as internally and in the context of its relations with its partners.

In doing so, its permanent objective is to reduce work accidents and to guarantee a sustainable process of improvement of Health, Security and Environment, which will provide to take over all the risks associated to our business.

The Hospitals' Central Pharmacy is committing to :

- **Comply** with legal and regulatory dispositions in terms of Health and Safety at work, and Environment.
- **Promote** a safety culture where every employee feels responsible and engaged.
- **Bring** down the occupational hazards by setting up the Single Occupational Risk Assessment Document at the Directorate General and its annexes.
- **Adopt** a proactive approach in order to guarantee to our staff, the best conditions of Health and Safety at work.
- **Make** sure that all the staff and the external participants respect the established instructions, procedures and rules in terms of Health, Safety at work, and Environment.
- **Protect** the environment within the framework of sustainable development.
- **Ensure** the clarity of the roles and responsibilities of the stakeholders in our office, in terms of Health, Safety and Environment.
- **Raise** awareness among all the staff, train and inform them in order to acquire the necessary knowledge in terms of Safety at work.
- **Digitize** documents and management procedures to ensure a transition toward digital and ecological practices.
- **Ensure** a continuous improvement of business performance in terms of Health, Safety, and Environment.
- **Improve** emergency plans and allocate appropriate means and adapted resources to ensure a rapid, effective, and integrated response, in order to minimize the consequences of any accident or major event.

I count on all my collaborators to contribute significantly to the improvement of health systems and to embrace this policy with enthusiasm and determination.

Health and safety at work is everyone's concern

The General Manager

MINISTÈRE DE LA SANTÉ — Pharmacie Centrale des Hôpitaux P.C.H

Dr DJERROUD SABRI

DIRECTEUR GÉNÉRAL

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Source : Internal document of PCH

Appendix I : Temperature Deviation and Quality Impact Assessment

FORMULAIRE D'ENREGISTREMENT	Référence : FOR-TRG -09
Déclaration des déviations de température et impact sur la qualité	Version : 03
	Date d'application : 09-02-2020
	Page : 1 sur 1

Réf : ..../DTR/DG/20...
Date :
Pièce(s) Jointe(s) : Courbe de température (... nombre de... page)

T° de conservation :

☐ Enregistreur de température non exploitable (Produit(s) en quarantaine)
☐ Enregistreur de température exploitable

Madame, Monsieur :

Après exploitation des enregistreurs de température accompagnant l'expédition du(es) produit(s), il ressort ce qui suit :

N°	N°Facture	Fournisseur	Date et heure de réception	Désignation du produit DCI-forme et dosage	Lot N°	Date et Heure de Déviation- T° minimale et/ou maximale	Durée Totale hors spécifications
1.							

Meilleures salutations.

Etabli par : Vérifié par : Visa du Directeur Technico-réglementaire :

Destinataires :

DSD:

-Positionner le produit lors de la déviation et son emplacement au moment de la déviation
-Lettre de réserve au dernier transporteur de la marchandise
-Police d'assurance

DFC :
-Information et suivi

DC :
- à titre d'information

DAM - DA RCD-DM
-Situer les responsabilités (INCOTERM)
-Statuer sur le transfert des propriétés
- Surseoir au paiement
} pour une éventuelle réexpédition ou incinération

Réf : ..../DTR/DG/20.... Date :
Pièce(s) Jointe(s) :-Notification de conformité
-Notification de non-conformité

Impact sur la qualité:

N°	Désignation du produit DCI-forme et dosage	Lot N°	Condition de conservation durant le transport
			Statut : (Conforme ou Non conforme)

Meilleures salutations.

Etabli par : Vérifié par : Visa du Directeur Technico-réglementaire :

Source : Internal document of PCH

Appendix J : Temperature Deviation Reporting Form

FORMULAIRE D'ENREGISTREMENT	Référence : FOR-TRG -09
Déclaration des déviations de température	Version : 02
	Date d'application : 07-07-2019
	Page : 1 sur 1

Ref : ………../DTR/DG/20…
Date :
Pièce(s) Jointe(s) : Courbe de température (…nombre de…page)
T° de conservation :

Madame, Monsieur ;

Après exploitation des enregistreurs de température accompagnant l'expédition du(es) produit(s), il ressort ce qui suit :

N°	N°Facture	Fournisseur	Date et heure de réception	Désignation du produit DCI-forme et dosage	Lot N°	Date et Heure de Déviation- T° minimale	Date et Heure de Déviation - T° maximale
1.							

Meilleures salutations.

Etabli par : Vérifié par : Visa du Directeur Technico-réglementaire :

Destinataires :

DSD:

-Positionner le produit lors de la déviation et son emplacement au moment de la déviation
-Lettre de réserve au dernier transporteur de la marchandise
-Police d'assurance

DFC :
- Information et suivi

DC :
- à titre d'information

DAM - DA RCD-DM

-Situer les responsabilités (INCOTERM)
Statuer sur le transfert des propriétés
- Surseoir au paiement

} pour une éventuelle réexpédition ou incinération —

SOURCE : Internal document of PCH

Appendix K : Temperature Data Logger Discharge Form

FORMULAIRE D'ENREGISTREMENT	Référence : FOR-TRG -08
Décharge des enregistreurs de température	Version : 00
	Date d'application : 28-01-2019
	Page : 1 sur 1

DECHARGE N°...... /20..

Je soussigné(e) Madame / Monsieur :..Fonction: ....

Certifie avoir remis ce jour le : / /

(Nbre) enregistreurs de température accompagnant l'expédition du(es) produit(s) suivant(s) :

N°	Externe ou Interne	Heure d'arrêt	N° de palette	N° de coli	Référence de l'enregistreur	Défectueux (Oui/Non)	Date et heure de réception	Facture N°	Fournisseur	DCI-Forme-dosage	Lot N°	Observation
1.												
2.												

Visa Direction /Technico-réglementaire

Je soussigné(e) Madame / Monsieur :..Fonction: ....

Fournisseur : ....

Certifie avoir reçu ce jour le : / /

(Nbre) enregistreurs de température accompagnant l'expédition du(es) produit(s) cités dans le tableau ci-dessus.

Cachet et Visa du Fournisseur

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SOURCE : Internal document of PCH

Appendix L : Cold chain risk Mapping

FORMULAIRE D'ENREGISTREMENT	Référence: FOR-SMQ-22
CARTOGRAPHIE DES RISQUES	Version: 00
	Date d'application: 30/10/2018
	Page 1 sur 1

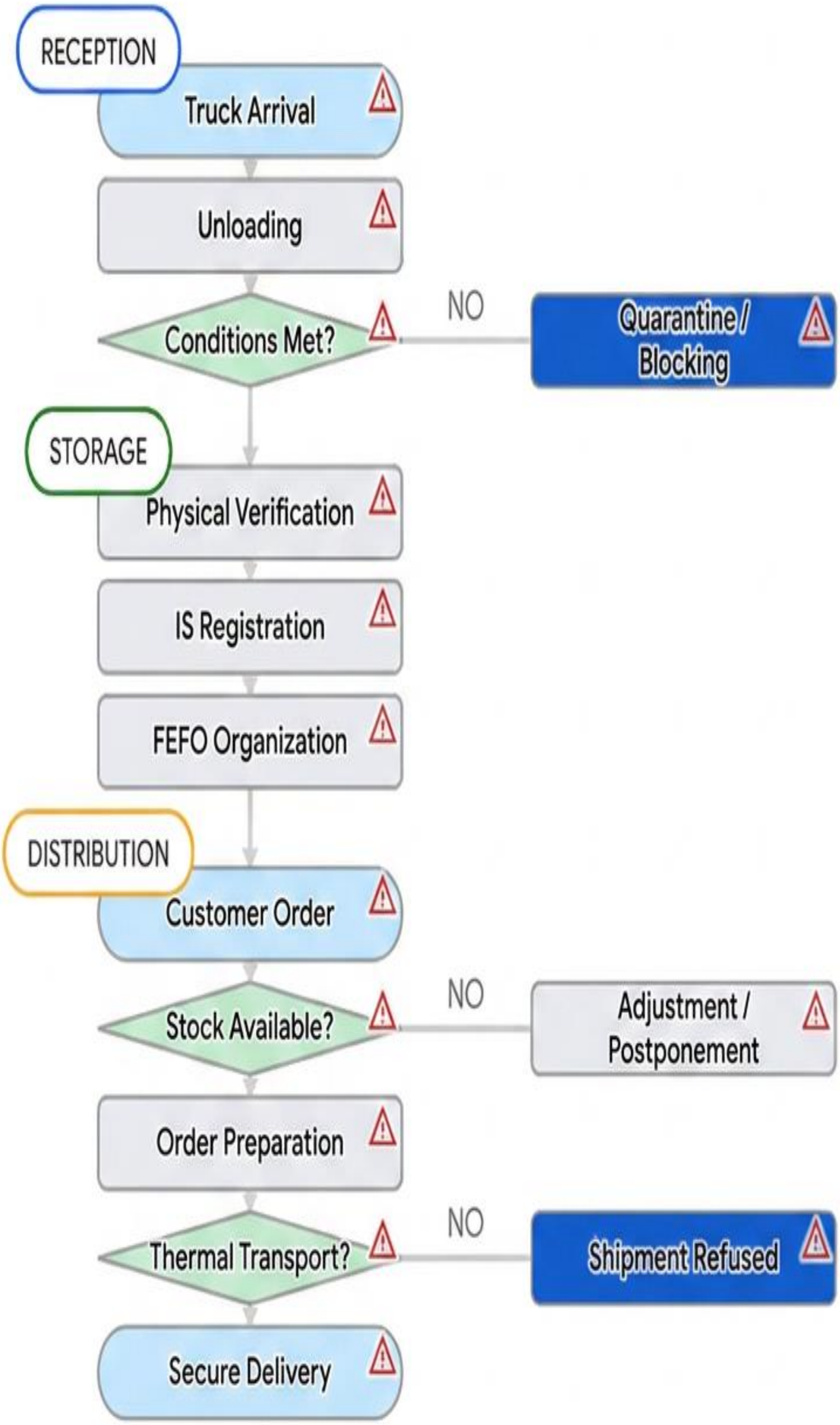
CRITERES D'EVALUATION DES RISQUES:	I: Impact (gravité, criticité)	V: Vraisemblance (probabilité, fréquence)	Pr: Priorité (hiérarchie)
	Echelle: de 1 à 4	Echelle: de 1 à 4	Echelle: de 1 à 3

V \ I	1	2	3	4
1	N3	N3	N3	N2
2	N3	N2	N2	N2
3	N3	N2	N1	N1
4	N2	N2	N1	N1

PROCESSUS	RISQUES	CONSEQUENCES	MESURES DE PREVENTION EXISTANTES	EVALUATION			PLAN D'ACTION				EVALUATION DES RISQUES RESIDUELS			CONCLUSION
				I	V	Pr	ACTION A ENGAGER	RESPONSABLE	RESSOURCES	ECHEANCE	I	V	Pr	
TECHNICO-REGLEME	Dysfonctionnement des chambres froides	Non-conformité des P,P Rupture de stock au niveau des S,S	Contrôle régulier des moteurs de la chambre froide	4	1	N2	Etalonnage des chambres froides	GOV / GLS	BUDGET					

Source : Internal document of PCH

Appendix M : Distribution Circuit and Integrated Risk Management Map



Source : Developed by personal efforts .