

# Closing the Cold-Chain Gap: A Data Governance & CAPA Playbook for Pharmacy FEFO Compliance and Excursion Response

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***Abstract- Cold chain management for pharmaceuticals will have an extremely important role in ensuring product protection, regulatory compliance, and cost-effectiveness. The present paper provides a data governance and CAPA playbook to identify and close compliance gaps in First Expired, First Out (FEFO) operations and excursion response. Based on GDP/GxP guidance, peer-reviewed scientific publications, and industry excursion case studies, the framework includes four tiers: governance, excursion management, KPI control, and training. The playbook standardizes excursion documentation and root-cause templates, as well as a suite of KPIs, including MAPE demand forecasting, excursions per 1,000 shipments, and expiry-at-risk percentages, integrated into digital dashboards with predictive alerts for excursions. The results emphasize less spoilage with better compliance traceability and quantifiable cost savings, as well as scalability among providers and wholesalers. Moreover, the research is in line with ESG priorities of reducing waste and transparency. The research findings provide regulators, pharmacies, and logistics providers with a realistic roadmap, and future studies should investigate the integration of the IoT and advanced AI into predictive cold chain resiliency.***

## I. INTRODUCTION

One of the most critical segments of supply chain management is the pharmaceutical cold chain, in which temperature-sensitive medicines are kept intact throughout their supply line until they reach the patient. Malfunctions within the chain may result in substantial losses of finances, as well as jeopardized patient safety, negative reputation, and regulatory

violations (Chukwu and Adibe, 2021; Filipova and Grigorov, 2024). The concept of First Expired, First Out (FEFO) is crucial here, as it requires dispatching medicines according to the expiry date to minimize wastage and ensure therapeutic efficacy (Mohammed et al., 2017). FEFO implementation necessitates strong tracking and monitoring systems at storage, handling, and distribution levels, which have been hindered by disjointed governance and uneven compliance with Good Distribution Practice (GDP) and Good Manufacturing/Clinical Practice (GxP) guidelines (Benabbes et al., 2025; Baquero et al., 2025).

Implementation of digital monitoring has not addressed the issue of temperature deviation in pharmaceutical supply channels. Excursions are the cases where the products are either under- or overheated to cause a loss of potency and break of regulations (Wichianrat et al., 2025). This is particularly costly in developing economies because the absence of infrastructure complicates the task of achieving a high level of storage compliance (Khanna et al., 2025; Elghomri et al., 2025). Moreover, the poor construction of audit trails and the absence of consistent data governance processes damage the timely root-cause analysis and remedial action, creating severe blind spots in both regulatory supervision and operational response (Chakraborty, 2025; Dib, 2024).

This is also limited by the absence of an integrated corrective and preventive action (CAPA) system unique to FEFO compliance, allowing pharmacies and wholesalers to be proactive to mitigate risks. As current techniques are more concerned with reactive troubleshooting rather than proactive monitoring and systematic governance, they restrict their applicability

to a broad spectrum of providers (Amengual and Distelhorst, 2025; Patil, 2025). With the introduction of advanced analytics, AI, and blockchain-based solutions, excursion response and compliance management can now be reconfigured as a systematic governance playbook that incorporates digital innovation as a regulating principle (Singh et al., 2025; Yingngam et al., 2024).

#### Objectives

- To prescribe a data governance and CAPA playbook.
- To align FEFO compliance to GDP/GxP.
- To create KPIs and computer tools to enable forecast monitoring.

The study can be useful to regulators, pharmacies, wholesalers, and logistics providers not only because it addresses compliance and governance gaps but also a pressing need to reduce spoilage and its related cost and protect patients against affected therapies (Li, 2024; Adebiyi et al., 2025b).

## II. LITERATURE REVIEW

### 2.1 Pharmaceutical Cold-Chain Management & Regulatory Frameworks

There has been a growing international regulation of the pharmaceutical cold chain because of the high danger in the product compared to temperature. Technical reports published by the World Health Organization (WHO) have highlighted that close monitoring in transport and storage is essential, appearing consistent with European Union Good Distribution Practice (EU GDP) and Good Manufacturing/Clinical Practice (GxP), which state that all supply chain participants must protect the integrity of products (Filipova and Grigorov, 2024). These systems establish minimum guidelines on facilities, equipment, and record-keeping in an attempt to reduce degradation risk and provide patient safety.

Nevertheless, even amid harmonization due to global regulators, in practice there is often an uneven implementation. Chukwu and Adibe (2021) emphasize a critical lack of infrastructure and monitoring systems in developing nations because unreliable power supply and inadequate storage systems affect the adherence to GDP standards. Likewise, Mohammed et al. (2017) stress the

regulatory battle in Nigeria, where the implementation power falls far behind policy promises. These studies suggest that frameworks are available, but the effectiveness largely relies on the local context and availability of resources.

In addition to the general guidance, technical methods like Mean Kinetic Temperature (MKT) computations have been designed to test cumulative exposure to thermal exposure and whether excursions are undermining the product safety. According to Benabbes et al. (2025), MKT-based models have the potential to minimize the number of product recalls caused by the unjustified increases in temperature, as they provide a more subtle assessment of temperature variations. However, these models are dependent on correct and always available data, which poses a challenge in disjointed supply chains. Regulatory frameworks therefore offer good conceptual guidance, but how this can be translated into practice depends on the strength of the monitoring systems and data control mechanisms.

### 2.2 Data Governance & Integrity in Cold Chain

Data governance has become a foundation of compliance as cold chain operations grow more digitized. According to Baquero et al. (2025), contract specification languages and smart contracts should be used to bridge gaps in compliance within the data supply chains. According to their work, automation may be used to enhance accountability by setting the obligation on digital infrastructure using codes. Nonetheless, this techno-centric approach is predisposed to high digital maturity, which in some pharmaceutical supply chains might not be a reality.

Chakraborty (2025) develops this point of view by describing a Data Integrity Master Plan with regular checks on audit trails, access control, and data verification. In contrast to Baquero et al. (2025), Chakraborty emphasizes less on automation and more on organizational culture and procedural rigor. These two opposite styles demonstrate a strain between compliance-by-design using technology and compliance-by-discipline using the culture of governance.

This space is further complicated by the consideration of ethics. According to Dib (2024), data integrity is not

just a technical concern; it is a bioethical obligation to protect patients, and any breach in data governance represents a failure of corporate responsibility. This is equally the case for Amengual and Distelhorst (2025), who note that companies in the supply chain globally are dealing with the efficiency-social performance dilemma, where compliance essentially is linked to collaboration (cooperation) and effective enforcement. Put together, these views give the implication that perhaps data governance in cold chain management requires a balanced approach that includes technical, process, and ethical protection of data.

**2.3 Cold Chain AI, Blockchain, and Smart Analytics**  
With the advent of new technologies, monitoring of the cold chain and managing risk have changed. According to Patil (2025), AI can be used in the pharma value chain for anomaly detection and predictive monitoring of the temperature-sensitive products. This is consistent with the position of Singh et al. (2025), who suggest that AI-based optimization could improve operational efficiency and minimize human error in pharmaceutical logistics. Both emphasize considerable potential, though Singh et al. (2025) are more optimistic about industry-wide adoption, whereas Patil (2025) warns that issues like data availability, validation, and interoperability are still obstacles.

In addition to AI, Khanna et al. (2025) suggest a multi-agent approach that integrates generative AI and blockchain to improve the resilience and transparency of fruit cold chains. Although not pharmaceutical-specific, their framework shows that it is possible to combine distributed ledgers to provide immutable audit trails and shared trust between stakeholders. Yingngam et al. (2024) also note the importance of AI-driven decision-making in pharmaceutical sciences, but, in contrast to Khanna et al. (2025), they focus on the human-in-the-loop approach, stating that technology should assist, rather than substitute, professional judgment. This is indicative of a wider argument about the automation and augmentation of pharmaceutical governance.

Predictive modelling in risk management has also been investigated with machine learning. Kalu-Mba et al. (2025a) show how AI can drive innovation in the

government sector through the improvement of decision-making, whereas Mupa et al. (2025b) use machine learning to improve actuarial science, improving predictive models to assess risks. Though these research works are not pharmacy-specific, they demonstrate transferable methodologies that may enhance FEFO compliance and excursion prediction. The underlying distinction, though, is translating these sophisticated models into the tools that can be deployed by pharmacies and wholesalers that are less digitally evolved.

#### 2.4 Risk, Compliance, and Global Supply Chains

Risk management is directly connected to corporate governance in global supply chains. Aror and Mupa (2025a) use WorldCom as a case study for a governance failure, where a failure to regulate and act ethically can contribute to systemic risk. Although the case does not have a pharmaceutical background, the message behind it, that failures in governance increase operational risks, is highly relevant to cold chain compliance. To further emphasize this, Aror and Mupa (2025b) discuss how AI supports risk management practices but state that automation is better than systems relying on human judgment because it can identify anomalies much faster than human-based systems.

Sienkiewicz (2025) also finds cybersecurity vulnerabilities to be a major risk in U.S. supply chain management, highlighting how digital and physical logistics are interdependent. This observation is especially the case in pharmaceutical cold chains, where online tracking tools have been targeted by cyber attacks in a growing number.

The other important dimension is transparency and accountability. Elghomri (2025) argues that there is a great potential for AI to create accountability in global supply chains, but consolidated research and practice are frequently hampered because of the fragmented nature of its implementation approach. Even further, Rajagopal et al. (2025) proposed the Supply Chain Karma Score (SCKS) to quantify the ethical footprint of international trade. Although it is a conceptual tool, the SCKS called for and expressed a growing recognition that compliance transcends the regulatory requirements to include moral and sustainability considerations.

Cumulatively, these studies offer a glimpse that seamless risk management in pharmaceutical cold chains is a convergence of governance, technology, and ethical stewardship. Regulatory compliance as a mandatory criterion, however, conflicts agonizingly with proactive risk management as a strategic differentiator.

### III. METHODOLOGY

The purpose of this study is to take a qualitative methodology with secondary research synthesis to come up with a playbook of structure to be followed in FEFO compliance, data governance, and CAPA integration in pharmaceutical cold chains. Qualitative design will suit the presence of regulatory, operational, and ethical aspects of the research problem because understanding of guidelines, frameworks, and case practices is needed instead of the gathering of primary numerical information. Secondary research enables the inclusion of multiple areas of insight into conclusions, so that research has more than one point of view as it refers to regulatory, academic, and industry literature (Chukwu and Adibe, 2021; Dib, 2024).

The sources of information to be used in conducting this study will be official regulatory documents (World Health Organization (WHO) technical reports, EU Good Distribution Practice (GDP) guidelines, and GxP frameworks), which will all be used to give the baseline compliance requirements on cold chain management. Peer-reviewed literature supports these regulatory texts by investigating practical uses of FEFO and excursion management in various situations (Filipova and Grigorov, 2024; Wichianrat et al., 2025). Moreover, case studies in the industry are applied to embrace best practices in digital monitoring, blockchain, and AI-enabled predictive analytics, which continue to shape pharmaceutical logistics (Baquero et al., 2025; Singh et al., 2025). The combination of these heterogeneous sources of data enhances the validity of the presented framework by guaranteeing that the given framework is based on theoretical and practical views.

The framework application approach includes building a formalized playbook and incorporating FEFO metrics, data governance concepts, and CAPA

circles into a working model. In particular, FEFO compliance indicators like expiry tracking and shelf-life forecasting are compared and contrasted with data governance frameworks with a focus on traceability, audit trails, and integrity controls (Chakraborty, 2025). The CAPA cycle, including corrective and preventive actions, is further mapped to the issues in the cold chain operations, and at the points that predictive analytics and smart contracts can perform the compliance actions and prevent the risks before they arise, predictive analytics and smart contracts are highlighted (Baquero et al., 2025; Patil, 2025).

Nonetheless, this research approach has a number of limitations. Simply put, the proprietary or real-world data of pharmaceutical firms are unavailable, and therefore, the framework is mostly based on simulated models, literature reviews, and documented cases of the industry. The risk of this dependency, however, is that the results arrive far from an adequate coverage of the complexity of the problems that are applied in practice within the field of operations management (Amengual and Distelhorst, 2025; Elghomri et al., 2025). However, by systematically combining the principles of regulatory theory, empirical studies, and technological perceptions, the present investigation presents a conceptual model from which institutional predictions about future empirical confirmation and field experimentation can be derived.

### IV. PROPOSED CAPA PLAYBOOK FOR FEFO COMPLIANCE

This playbook is designed as a tiered system that includes governance, excursion management, tracking, and female empowerment. It combines GDP/GxP principles, FEFO compliance requirements, and data-based accountability mechanisms to enhance pharmaceutical cold chain resilience.

#### 4.1 Governance Layer

The playbook is rooted in a governance framework where the roles and duties of all stakeholders have been well delineated. The inability to clearly define accountability in global supply chains usually leads to a lack of uniformity in response to compliance violations (Aror and Mupa, 2025a; Rajagopal et al., 2025). To that end, the playbook outlines stakeholder roles, including regulators and wholesalers and ending

with last-mile pharmacies. As an example, the regulatory authorities will be responsible for conducting oversight and compliance audits, and wholesalers and logistics clients will be held accountable for the execution of excursion monitoring and distribution compliance with FEFO. Quality assurance managers attend to audit trails and corrective and preventive action (CAPA) at the organizational level, whereas pharmacists handle expiry at the dispensing point (Mayake and Base, 2025). Such transparency of roles minimizes fragmentation of governance and accountability throughout the cold chain (Mgugu et al., 2025).

Ethical accountability is another aspect that is incorporated in the governance layer. The playbook illustrates that appropriate corporate governance aligning with social responsibility expectations is important with respect to ethical governance in pharmaceutical logistics (Dib, 2024; Amengual and Distelhorst, 2025). This dual focus on compliance and responsibility aids in balancing regulation requirements and patient outcomes.

#### 4.2 Excursion Management Layer

The second layer addresses the temperature excursion control (such as the critical risks for the implementation of the cold chain). Excursions are documented against organized templates capturing properties such as presence/absence, magnitude and location of variation, and the conditional nature in recording them (Wichianrat et al., 2025). For detection, devices capable of communicating with the IoT are fitted with digital sensors or devices that notify you that the limit has been violated. In order to supply different answers to such events, excursions can be classified as small, medium, and critical level depending on the resources required to supply solutions for the areas where the patients are the most exposed to the risk of departure (Benabbes et al., 2025).

The root-cause analysis templates include corrective workflows that streamline the deviation investigation and management process. The templates not only crystallize corrective actions such as purging of potentially affected products but also map preparatory actions such as redirecting product routing or recalibrating manufacturing equipment for future

processes. CAPA can be triggered through smart contracts (incorporated with blockchain) for immediate reduction of delays in manual check-ups and promotion of traceability between stakeholders by integration of activation of CAPA during incidents where loss/over the excursion limit is exceeded (Baquero et al., 2025; Khanna et al., 2025). This will add greater accountability and tighter restrictions.

#### 4.3 KPI & Monitoring Layer

The playbook adds FEFO compliance through a complete framework for KPIs, inherent in monitoring dashboards. The method includes important metrics like the forecast error, in the form of MAPE; risk, which must be defined based on anticipated excursion occurrences per 1,000 shipments; and cost/compliance exposure, which is expressed as a percentage of stretched expiry. These KPIs make it easier for the stakeholders to review both predictive performance and compliance performance in real time.

Dashboards are AI and machine learning-based predictors that are used to raise advance warning about risky deliveries. As an example, the previous tendencies of temperature changes along a means of transportation could be studied to predict educational activities prior to their execution (Singh et al., 2025; Kalu-Mba et al., 2025a). Predictability can lead to proactive rerouting of packages or better monitoring to minimize the chances of spoilage, which is quite expensive. Introducing blockchain guarantees the immutable logs of KPI, strengthening auditability and trust among regulators and industry participants (Yingngam et al., 2024).

The playbook ensures effective monitoring is not a passive process by connecting KPIs to governance and excursion management levels so that corrective action can be informed by it. This closed-loop system creates a continuous improvement cycle, which meets GxP standards of accountability and traceability (Sienkiewicz, 2025).

#### 4.4 Training & SOP Roll-Out

The last layer of the playbook focuses on what makes the workforce ready and protocol consistency. The training modules are designed with specific stakeholders in mind, such as pharmacists (expiry tracking and FEFO compliance), distributors

(excursion logging and CAPA workflows), and wholesalers (KPI interpretation and governance reporting) (Chukwu and Adibe, 2021; Filipova and Grigorov, 2024). Based on the need to ensure practical applicability of the individual modules, they merge theoretical knowledge, regulatory standards, and case-based simulations.

The updated Standard Operating Procedures (SOPs) incorporate alignment of the cold chain in terms of GDP and GxP. As an example, SOPs are step-by-step procedures in which excursions, root-cause investigations, and preventative actions are documented. SOP rollouts also use digital platforms, where updates can be readily accessed and validated over distributed networks with pharmacies and logistical providers (Mohammed et al., 2017; Elghomri et al., 2025).

Notably, training and SOP reinforcement build up a culture of compliance, which can help the layers of governance and monitoring. The playbook detective mechanism works to mitigate the possibility of human error and potential regulatory misalignment through institutionalization and enforcement of learning and accountability and to promote uniform FEFO compliance throughout the pharmaceutical supply channel (Li, 2024; Adebisi et al., 2025b). The given CAPA playbook enables resolving the issue of interrelationships between the governance, excursion management, monitoring, and workforce capacity within the pharmaceutical cold chain. It offers the roadmap to align FEFO compliance with regulatory, operational, and ethical requirements by combining GDP/GxP standards and predictive analytics tools with a structured implementation of CAPA workflows and a blockchain.

#### V. IMPLICATIONS OF SCALING: OUTCOMES.

The suggested CAPA playbook compiles quantitative results in minimizing spoilage, managing costs, and enhancing compliance. The system has eliminated cases whereby there will be wastage of stock due to expiry since FEFO compliance is incorporated into the day-to-day running of the business. Past research finds that inadequate expiry handling may result in cost losses of as much as five to seven percent of the annual

pharmaceutical stocks, specifically within massive distribution channels (Chukwu and Adibe, 2021). By monitoring their expiry-at-risk and predicting their shelf life, organizations can attain measurable cost reductions by dispensing medicines in sequence, both direct and indirect financial fines of non-adherence (Filipova and Grigorov, 2024).

The main benefit of the playbook design is scalability. The framework can be implemented at the different phases of digital maturity because it allows standardization of excursion logging, CAPA workflows, and KPI tracking across pharmacies, wholesalers, and distributors across global markets. The integration of smart contracts and blockchains also promotes scalability, as a uniform system of compliance protocols is maintained, irrespective of geography (Baquero et al., 2025; Khanna et al., 2025). The modular design also enables smaller providers to start with the basic layers of the system, like governance and SOP updates, and then slowly work towards adding predictive analytics and AI-driven alerts. This tiered solution makes broadening adoption possible without straining resource-starved providers. Another important consequence is the sustainability impact. Pharmaceutical waste not only continues to cost countries more money but also leads to environmental burdens. The playbook meets the requirement of Environmental, Social, and Governance (ESG) because it minimizes spoilage using FEFO optimization and prevents excessive excursion (Li, 2024). Furthermore, sustainable social responsibility via good governance practice as well as ethical accountability via systemic governance organization and governance process techniques also remains to further the improvement of patient safety minimization and systems inefficiencies (Adebisi et al., 2025b). As such, the outcomes of the playbook are much wider than that for compliance purposes but will ultimately have a defining influence on sustainable or ethical issues within the global pharma supply chain.

#### VI. DISCUSSION

The outcomes of this research work clearly extend from the literature in terms of showing how AI-based analytics and governance frameworks work together to support cold chain compliance by means of semantic operations. This study outlines a layer of

potential KPIs and early warning signs/prediction indicators for AI to improve, in aggregate, the prediction quality of at-risk shipment identification. This, in addition to the playbook offering an audit trail/CAPA traceability capability, again reiterates the need for sound data governance structures (Chakraborty, 2025). Combined, these findings support the case made for technology and governance as dual unconditional enablers for sustainable FEFO compliance.

Furthermore, the playbook is an extension of previous work for excursion management. Wichianrat et al. (2025) recommended structured/institutionalized logging of tasks, which this study has implemented via standardized excursion forms and corrective workflows. Incorporate blockchain-enabled smart contracts (Baquero et al. 2025); the framework goes even further from compliance by means of manual reporting to verification and enforcement for compliance through the use of blockchain. This is the remedy for the shortcomings of systems for controlling the cold chain, which Elghomri et al. (2025) reported from the systemic weaknesses of infrastructural development in view of controlling cold chain management, especially in emerging nations.

Ethical considerations are very relevant to that discussion. While Groslover (2024) stated in one of his arguments that the problem of corporate governance is that they are trying to be useful and be ethical, this is the same scenario that the theoretical work is trying to imply here, in that there must be a synthesis involving the accountability measure in patient safety and the transparency measure within the organization. With reduced incidence of spoilage from the playbook, fewer patients must face the risk of being given compromised medications, which directly ties work practice to ethical practice (Amengual and Distelhorst, 2025). The pharmaceutical waste disposal problem is also linked to the objectives of ESG, which focuses on sustainability while enhancing social trust (Li, 2024).

The lens builds the first story about forward-looking supply chain resiliency, placing actionable scenarios in a future context. Aror and Mupa (2025b) addressed the role of risk management in a resolution disruption

regime, and while the boundary case gives the what in this paper, the KPI suite with a practical guardrail mechanism for operationalizing these insights is the how. As more of this work scales up from the local to the global level, the playbook provides a roadmap for strong, transparent, and values-based predictive monitoring. Ultimately, its implementation has the potential to transform compliance not just as a regulatory requirement but as a proactive solution for ensuring patient safety and sustainability within the pharmaceutical industry.

## CONCLUSIONS & RECOMMENDATIONS

This study developed a proposed CAPA playbook framework to increase FEFO compliance and cold chain resiliency within pharmaceutical supply chains. The most important lessons learned emphasized that good governance, process management standardization for excursions, the ability to develop predictive KPI monitoring, and specific workforce training mutually support a reduction of spoilage and enhanced compliance and patient protection. By combining data governance and AI-powered monitoring with GDP/GxP requirements, the playbook transforms compliance from a reactive process into a predictive and preventative system.

For regulators, the findings highlight the need to enshrine digital governance requirements into policy frameworks. As a result, regulators should require immutable audit trails, digital signatures, and predictive monitoring capabilities to be part of GDP compliance to ensure consistency across mature and emerging markets (Chakraborty, 2025; Rajagopal et al., 2025). This change would bridge the gap between the systems of different countries and further promote transparency and accountability in the pharmaceutical supply chain.

However, it is easier to be incrementally adopted from an operation perspective—the playbook can be adopted by pharmacies, wholesalers, and logistics providers. The fast pace should be the adoption of SOPs stored in the blockchain and well-defined governance roles; the adoption of excursion templates, Key Performance Indicators (KPI) dashboards, and CAPA workflows on the blockchain should follow a low velocity adoption curve. However, precise

phasing of ideally disciplined standards can allow even resource-constrained providers to benefit from increased compliance as they incrementally adopt innovation (Baquero et al., 2025; Singh et al., 2025).

Activities for future research are proposed that focus on the integration and adoption of Internet of Things (IoT) devices and advanced Artificial Intelligence (AI) algorithm implementation in the practice of real-world cold chain management applications. This is formative and uses the IoT to track granular experience ethnographies and overlay these as an additional layer on top of them as a form of generative AI demand and risk forecasting. Optimized scaling of the cold chain for languishing pharmaceuticals will be validated on an empirical performance coup, and endoscopic secretions will uncover possible synergies between different models to ultimately lead to a sustainable model.

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