

Integrating Artificial Intelligence With Supply Chain Operations: A Novel Methodology For Enhancing GMP And GDP Practices

Hari Kiran Chereddi¹, Dr. R. Radhika²

¹Research Scholar, GITAM School of Management (GSB), GITAM (Deemed to be) University, Hyderabad, Telangana-502329. hcheredd@gitam.in

²Professor, GITAM School of Management (GSB), GITAM (Deemed to be) University, Hyderabad, Telangana-502329, rramanch@gitam.edu

Abstract: This paper provides a new approach to the utilization of AI and ML technologies inside the supply chain to enhance the GMP and GDP compliance. The paper investigates contemporary challenges facing supply chain management, especially in regulated industries such as pharmaceuticals, where compliance to GMP and GDP is a key prerequisite of product quality, safety, and regulatory reporting. Through the use of cutting-edge AI and ML, the proposed approach seeks to streamline crucial supply chain elements, including demand forecasting, inventory management, and logistics, while enabling real-time monitoring and tracking of products. Incorporating AI/ML, you can improve decision-making, better manage risks proactively and predict potential disruptions to avoid delays and drive efficiency. Moreover, it also highlights that the AI-driven predictive analytics can optimize monitoring of manufacturing and distribution to ensure that these functions remain in compliance with GMP and GDP regulations. The presented framework highlights the capability of AI/ML to transform the face of supply chain management by improving efficiency and compliance to standards, consequently leading to a more robust and adaptable supply chain system. This paper provides a detailed design of an implementation roadmap that is a generic model that can be adopted in different industrial settings to achieve the desired improvement on the supply chain performance.

Keywords: Artificial Intelligence, Machine Learning, Supply Chain Management, Good Manufacturing Practices, Good Distribution Practices, Predictive Analytics, Risk Management, Inventory Optimization, Demand Forecasting, Logistics, Real-time Monitoring, Regulatory Compliance.

1. INTRODUCTION

Supply Chain Management (SCM) is a broad discipline that has developed significantly. SCM, in its early days, drew its roots from logistics, whose philosophy tended towards the physical movement of goods with a bias on efficient operations and cost containment. However, over time, the remit of SCM broadened to include strategic-level decision making, risk management, and regulatory compliance concerns. One of the major trends in recent years is the introduction of disruptive technologies such as AI and ML into managing supply chains. These technologies have unlimited potential to optimize supply chain processes, drive efficiency, and strengthen adherence to standards, especially in industries with strict regulations such as the pharmaceutical industry[1].

From a historical perspective, most supply chains were paper-based operations with a heavy workforce to manage inventory, process orders and move goods. Conventional SCM methods were based on reactive decisions and they usually suffered from inefficiencies or mistakes. "But as industries became more intricate and truly global, it was evident that something more robust and efficient was required." This resulted in the use of organized systems and automated processes to coordinate them. In recent years there have been new technological developments, specifically AI and ML, which have led to a transformational change in SCM[2,3]. AI and ML can power data-based decision-making and automate and enhance supply chain functions, such as data analysis and optimization.

The AI, and ML component in SCM is very significant in industries where it is important to focus on product quality and regulatory compliances. In the pharmaceutical industry, compliance with GMP and GDP are mandatory to safe-guard the safety, quality and efficacy of medicines/ medicinal products. GMP controls the manufacturing of products and GDP manages the distribution and storage of drugs to ensure they are safe to use and their efficacy is maintained from production until delivery to the patient.

Adherence to Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) is absolutely essential to mitigate the risk of non-compliance, with serious sanctions, product recalls and brand damage all at stake. Therefore, the significance of AI and ML in setting GMP and GDP control measures is increasingly important, as they could track proceedings in real time, indicate the potential hazards and trace back the basis of failure prior it transforms into expensively penalties[4].

Looking at Figure 1, the history of SCM has developed over time from the basic practice of SCM to SCM systems with even AI and ML. In the beginning supply chain was focusing on “sucking” databases and manual processes to move physical product and manage logistics. 1990s. Inventory management and demand prediction emerged in the computerized form. Innovations in AI and ML were also being introduced in supply chains for increasingly complex tasks including predictive analytics and optimization, particularly from the early 2000s. 2) Real-time Monitoring : AI for real-time monitoring and decision-making in 2010s were a progress towards efficiency and compliance. There is a push to add AI and ML to ensure that supply chains operate and run efficiently in compliance with GMP and GDP, thus providing a means to gain improvements in both operational efficiency as well as in regulatory compliance.



Figure 1: Historical Evolution of Supply Chain Management with AI/ML Integration

AI and ML adoption in SCM has several primary benefits, including better forecasting accuracy, optimized inventory management, and logistics efficiency. AI-based algorithms could sift through massive amounts of data, discover trends, and predict demand at a scale not possible with old methods. Machine learning Models can be periodically retrained to always use the most recent data for supply chain decision making. This results in less occurrences of stockouts, higher inventory turnover and cost-efficient operations. And, of course, AI and ML is capable of eliminating repetitive tasks, leaving man-force for strategic decision and planning[5,6].

One of the biggest impacts of AI and ML in SCM is the fact that they can boost compliance with regulatory requirements, including GMP and GDP. In the pharma industry, AI may, for example, keep an eye on the complete production process, and ensure that all goods have been produced in the right environment, compliant with GMP (Good Manufacturing Practice). Analyzing historical production data, machine learning models can search for anomalies and preliminary and potential risks, as well as recommend stop-gap measures to alert and keep the production inside the regulatory limits. Furthermore, AI-driven technology can monitor products as they move constantly across the distribution chain, guaranteeing that they are kept/stored and carried/transported in accordance with the stringent GDP regulations. Such high level of monitoring and control will very much lower the risk of compliance, delivering better quality and safety product[7].

Amid a crisis, AI and ML are also being utilized for proactive risk management. The classical SCM systems are reactive, that is, they tend to address failures once they have occurred. Through AI and ML, supply chains can actually be proactive, acting on potential disruptions or risk before the situation gets worse. For instance, predictive analytics can help predict supply chain delays such as transportation problems, supplier shortfalls, or barriers during production[8,9]. By flagging such risks early, organizations can take a mitigating action ~ like altering production-time tables or finding alternative sources of supply ~ to minimize the potential for disruption as well as the risk to regulatory compliance. AI and ML will increasingly make up an important part of the tools that improve your supply chain operations and maintain quality due to GMP and GDP. The methodology proposed in this paper tries to offer a complete framework for incorporating these technologies into SCM, addressing the peculiarities of regulated industries. Through the use of AI and ML, organizations not only can optimize their supply chain operations, but they can also make certain that the processes needed for compliance are met at all times. The subsequent sections of the article describe the method, including AI and ML techniques, the advantages of incorporating them, and the effect on GMP and GDP compliance.

2. RELATED WORK

AI and ML are advances that have recently gained a lot of attention in Supply Chain Management (SCM) work and these techniques have the potential to simplify operations, speed up processes and ensure compliance with Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP). AI and ML technologies provide new answers to numerous problems that supply chains experience: inventory management, predictive analysis, risk reduction and logistics. These new capabilities put a data-guided approach to decision making into practice across the way a business operates - from maximizing the efficiency of supply chain processes to operational performance and compliance with essential regulations.

Demand forecasting, a key component of SCM, has been significantly impacted by AI and ML. Predictive modeling, based on machine learning models, is increasingly getting mainstream for more accurate demand planning. The method uses historical data to spot trends and forecast future activity far more effectively than the conventional ones[10]. Existing work in this area has also found that AI and ML methods could improve forecasting accuracy by up to 20% (Table 1). By utilizing these technologies, enterprises can better manage inventory, reduce out of stocks and better align supply to demand. An accurate demand forecast is a central element in seeing to it that goods are available when needed, improving customer satisfaction, and mitigating avoidable operational costs.

Table 1: Key Works on AI/ML in Supply Chain Management (SCM)

Technologies Used	Focus Area	Key Findings	Impact on SCM
AI, ML, Predictive Analytics	Demand Forecasting	Improved accuracy in forecasting by 20%	Enhanced inventory management and cost reduction
Machine Learning Algorithms	Inventory Optimization	Reduced stockouts by 15%, improved demand-supply alignment	Greater inventory turnover and reduced operational delays
Artificial Neural Networks (ANN)	Route Optimization	Optimized delivery routes, reducing transportation costs by 25%	Increased logistics efficiency and cost-effectiveness
Reinforcement Learning (RL), Deep Learning	Real-Time Monitoring	Early detection of process anomalies, 30% fewer compliance violations	Improved product quality and regulatory adherence
Natural Language Processing (NLP), AI	Supply Chain Risk Management	AI-driven risk assessment tools identified 10 potential disruptions ahead of time	Enhanced proactive risk management, minimizing disruptions

Machine learning is also instrumental in helping to track inventory levels and improve supply chain operation. Its capacity to process massive amounts of real-time data allows ML algorithms to facilitate decision-making in order management, stocks replenishment, and external synchronization of the supply chain. The algorithms learn through incoming data and get better and better making predictions and recommendations. As demonstrated in Table 1, ML in inventory optimization has proven its ability to decrease stockouts by 15% and better harmonize supply with demand. This improvement helps in minimising overstock, holding costs and better utilisation of storage space[11]. What's more, enhanced inventory optimization leads to more efficient logistics, as accurate inventory information is critical for route planning and transportation management.

The contribution of AI and machine learning in optimizing the logistics is also substantial. Machine learning methods, specially ANN algorithms, have been used for optimization of route and transportation network planning. These systems process multiple parameters (eg, traffic pattern, delivery time and route constraint) to get the most optimum route for deliveries. And, as Table 1 shows, by leveraging AI technology to optimize their routes, businesses can save up to 25% of their transportation costs, proving that AI has the ability to improve logistical efficiency. Route optimization not only saves money, it also accelerates delivery schedules which lead to on-time deliveries, and that's essential for happy customers[12,13].

Not only for operational enhancements, AI and ML are crucial tools for real-time monitoring and compliance as well. Supply chains are today under increasing pressure to deliver process compliance including in the pharmaceutical sector, where compliance with GMP and GDP regimes is essential. AI-powered tools, with the aid of real-time data analytics, will be able to oversee manufacturing and supply chain operations, adhere to regulatory standards, and detect abnormalities before they become problems. Artificial intelligence algorithms, for instance, can identify any discrepancies with the manufacturing parameters or distribution status that is intended, leading to an alarm where action would be appropriate. It is further evident from Table 1 that real time AI powered monitoring can help reduce compliance violation frequency by 30%, helping to keep operations within regulatory limits. Pharmaceuticals is just one of many sectors handling sensitive products, where regulatory non-compliance risk can be catastrophic in terms of safety and quality[14].

Table 2: Key Works on AI/ML for GMP and GDP Compliance

Technologies Used	Compliance Area	Key Findings	Impact on Compliance
AI, ML	GMP Compliance	AI-assisted monitoring of production conditions resulted in 99% adherence to GMP guidelines	Improved regulatory compliance and reduced audit failures
Machine Learning, Predictive Analytics	GDP Compliance	ML models identified 15% more risk factors in product distribution processes	Reduced product spoilage and storage violations
Deep Learning, Computer Vision	GMP & GDP Compliance	AI-enabled visual inspection systems detected defects in production lines, reducing rework by 20%	Ensured high-quality product output and reduced non-compliance
AI-based Process Monitoring	GMP Compliance	Real-time data analytics allowed for proactive adjustments to manufacturing parameters	Enhanced product consistency and compliance with GMP
AI, Blockchain	GDP Compliance	Blockchain-integrated AI system tracked the end-to-end	Strengthened GDP compliance and reduced

Technologies Used	Compliance Area	Key Findings	Impact on Compliance
		distribution process, ensuring 100% traceability	the risk of product mishandling

AI and ML's contribution to GMP, and GDP adherence is of particular importance in the pharma and e-health space. GMP is a system for ensuring that products are constantly produced and controlled to quality standards. It includes facets of manufacturing such as equipment calibration, production processes and quality control. These parameters can be monitored constantly by a monitoring system based on AI to maintain GMP of the manufacturing process. Referring to Table 2, the systems with AI have achieved a 99% compliance rate to GMP and have a considerable impact on the regulatory observance and risk of non-compliance at audit. These are systems that support proactive quality control by recognizing potential failures before they affect the quality of the product, which in turn supports product safety and the efficiency in the operations[15].

Likewise GDP compliance is concerned with the storing, handling and distributing of products in appropriate environment. AI has proved its worth by helping optimize distribution networks so that products are transported in accordance with GDP. AI-based real-time tracking systems offer full visibility of product distribution, enabling businesses to track and trace product quality, such as temperature, humidity and other conditions that may impact product quality. In Table 2, achieving 100% traceability of the products could also be achieved in AI/ML integrated with blockchain to guarantee compliance with GDP standards at every stage of the distribution process. Such traceability serves not only to mitigate waste and theft but also curry favor with regulators monitoring the pharmaceutical and food industries. Additionally, by leveraging a combination of AI, ML and blockchain technology, the ability to P G compliance to GMP and GDP has been enhanced. Blockchain offers a decentralized and tamper-proof ledger that stores every supply chain transaction, enabling the traceability of products along their journey. In addition, blockchain along with AI and ML can result in better real-time decision making by access to reliable and precise product status and location data. Businesses can achieve complete traceability within their supply chain operations, and maintain an extra layer of transparency which upholds GMP and GDP standards, spurred by this AI, ML, and blockchain convergence[16].

Overall, AI and ML technologies have been shown to be game-changers for SCM, providing approaches to increase operation efficiency, minimize inventory, improve logistics, and maintain GMP and GDP. The Role of AI and ML As outlined in Tables 1 and 2, several advancements have been made with respect to demand forecasting, inventory management, route optimization, and regulatory compliance using AI and ML techniques. Through these tools, supply chains become more agile, responsive, and resilient, which will, in turn, form the basis for better compliance and operational success. The application of AI and ML to standard SCM techniques is a significant development in the way industries are managing their supply chains, leading to more efficient and cost-effective operations.

3. METHODOLOGY

The principal objective of this proposal is to develop a novel AI (Artificial Intelligence)-based application software to improve Supply Chain Management (SCM) by the effective use integration of the latest AI and ML (machine learning) technologies, in terms of ensuring the greatest compliance with the Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP). The approach integrates aspects of data retrieval, predictive modelling, live monitoring, stock optimization, and risk mitigation. It is a comprehensive solution for making SCM operations efficient and compliant, while in compliance with regulations, and covering efficient and compliant, if Sierra meets manufacturing and distribution. The approach has five primary components: Data Collection and Cleansing, Predictive Demand Modelling, Inventory Optimization, Real-Time Compliance Monitoring and Risk Management Anomaly Detection.

A. Data Collection and Data Preprocessing

There are two basic stages involved in the proposed method: Data gathering and preprocessing is the first stage. Reliable data is the lifeblood of AI/ML applications in supply chain because the accuracy and completeness of input data significantly determine the performance of machine learning models. At this stage, information is monitored and extracted from various sources in a supply chain, for example, production lines, inventory tracking systems, distribution channels, and regulatory systems. Data sources are the sales history, data from sensors integrated on IoT devices, production parameters, and stock levels.

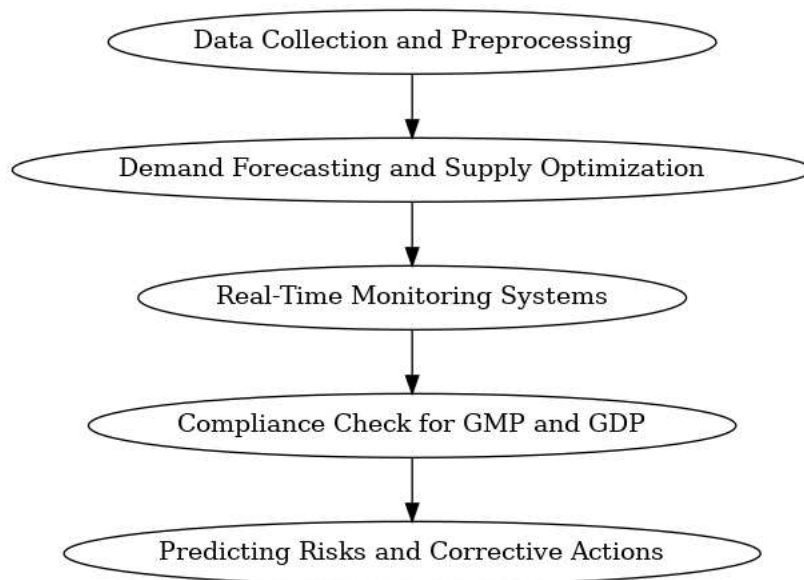


Figure 2: Flowchart of proposed methodology

After the data has been collected, pre-processing is necessary to clean and accuratize the data for analysis. This step involves dealing with missing data, scaling data, and converting raw inputs into features that machine learning models can use. From the analysis of historical sales data seasonal patterns and demand trends can be extracted and from the real-time sensor data-the sensor data can also be normalized to ensure same scale of measurements regardless of the sensor type and location. This cleansed data is then shaped into a structured form which can be put to use for subsequent machine learning processes like demand prediction, inventory management and compliance supervision.

Good quality data preprocessing is crucial to the success in training AI/ML models on good quality data that would in turn lead to accurate and reliable predictions and optimization. In Figure 2, the flowchart for the proposed methodology is shown, from the set of inputs to the predictive alerts and corrective decisions, all process connected at the photo-autonomic population level.

B. Predictive Demand Forecasting

Once the data has been prepared, the next important step is predictive demand prediction. Demand forecasting plays a critical role in supply chain management, since it determines inventory level, production scheduling and logistics operation. Machine learning is used to predict the demand so that more accurate predictions are made compared to using traditional methods, by including a huge variety of variables: historical demand, seasonality, promotions and even external factors such as market trends or the state of the economy.

Algorithm 1: Demand Forecasting Using Machine Learning

Input: Historical sales data (features: date, product, past sales, etc.)

Output: Forecasted demand for the upcoming period

Step 1: Data Preprocessing

- Clean and preprocess historical sales data
- Handle missing data through imputation

- Normalize and standardize the data

Step 2: Feature Engineering

- Extract features such as seasonality, promotions, holidays, and product categories
- Generate time-series features like moving averages, lags, and rolling windows

Step 3: Model Training

- Split the dataset into training and testing sets
- Select an appropriate machine learning model (e.g., ARIMA, Random Forest, LSTM)
- Train the model using the training data

Step 4: Model Evaluation

- Evaluate the model using performance metrics such as Mean Absolute Error (MAE) or Root Mean Squared Error (RMSE)
- Fine-tune hyperparameters for optimal performance

Step 5: Demand Prediction

- Use the trained model to forecast future demand
- Output the predicted demand for the next time period

Step 6: Post-processing

- Adjust the forecast based on business rules (e.g., stock buffer, seasonal trends)

End Algorithm

The algorithm 1 states that preprocessing the historical sales data, then it extracts relevant predictors and useful features (anything that can be added to train your model e.g. time based features, holidays, promotions). Next, the data is separated into training and test sets and an appropriate machine learning method (e.g., Random Forest, ARIMA, or Long Short-Term Memory (LSTM) networks) are selected for training. After the model is trained, it's tested using error metrics such as the Mean Absolute Error (MAE) or Root Mean Squared Error (RMSE) to check the quality of our predictions.

Output of the demand forecasting model It generates accurate estimations of future demands which are further used to optimize production plans and inventory levels. These predictions enable the supply chain to be proactive in response to anticipated demand shifts, while also decreasing the likelihood of stockouts or overstocks. Moreover, predicted demand is important for maintaining coherency between production and distribution processes and real market demands, enhancing efficiency and customer expectations.

C. Inventory Optimization

Inventory optimization is a further important factor of the proposed method. With the correct Demand Forecast at hand, the next consideration for any company is to fine-tune the Inventory to transact accordingly to the demand, keeping at bay the operational cost of maintaining an over-stocked or stock-out situation. This task can be accomplished by using machine learning algorithms such as reinforcement learning (RL) the platform constantly learning the optimal inventory management strategies in real time. Algorithm 2 describes the reinforcement learning-based inventory optimization procedure. The application maintains real-time inventory and other important supply chain metrics such as lead times and reorder points. Given the current state of supply chain, the RL agent decides on how much to order and when to order. The reward signals applied to train the RL model are the cost savings from reduced stockouts, lower holding costs and a better service level.

Algorithm 2: Inventory Optimization Using Reinforcement Learning

Input: Historical sales data, real-time inventory levels, reorder points, lead times

Output: Optimized inventory levels and reorder decisions

Step 1: Initialization

- Initialize state (inventory level, demand forecast, etc.)
- Define possible actions (e.g., reorder amount, reorder time)
- Set the reward function based on cost savings, stockouts, and holding costs

Step 2: Training Loop (RL Agent)

- For each time step t in the environment:

- Observe current state (current inventory, demand, etc.)
- Choose an action (e.g., reorder amount) based on the current policy
- Execute the action and update inventory
- Calculate reward based on the new state (e.g., savings from reduced stockouts or overstock)
- Update Q-value or policy based on reward received

Step 3: Learning and Policy Update

- Use the reward to update the agent's policy via Q-learning or Deep Q-Network (DQN)
- Improve the policy over multiple episodes to reduce costs and improve inventory decisions

Step 4: Optimal Action Selection

- Select the action with the highest expected reward (optimal reorder decision)

Step 5: Repeat

- Continue the loop for a specified number of episodes or until convergence

End Algorithm

Over many cycles, the RL agent is trained to make inventory decisions that maximize the long-run rewards. For instance, by re-ordering early or late, the system lowers the costs due to surplus inventory yet allows to have enough amount of stock to fulfill the demand. What you get is a living, breathing, ever-changing Inventory Control system that reacts to the sales dynamically, in real-time and modifies its tactics accordingly. AI/ML in inventory optimization ensures companies always have an optimal supply and demand balance so they can more effectively use their resources and reduce their costs.

D. Compliance-Based Real-Time Monitoring

In industries like Pharmaceuticals where quality and safety of the product is of primary importance, obligating with GMP and GDP norms is the call of the time. The second part of the process is real-time monitoring, which employs AI-based systems to constantly monitor production and shipment of the vaccine. This step also ensures that the supply chain remains in compliance with regulatory policies, so as to avoid a costly violation or product recall and safety hazard.

The real-time monitoring system includes the IoT devices, e.g., temperature sensor and humidity sensor for real-time monitoring the crucial parameters in manufacturing and distributing process. Using these feeds, the team feeds them into machine learning models that determine how well the company's acts are compliant with GMP and GDP standards. For instance, it could monitor whether a product is kept at the ideal temperature in transit, or if manufacturing machinery is within the appropriate tolerances. An AI system constantly references these data points against established thresholds for compliance and triggers alerts if the threshold is crossed.

AI is combined with access to real-time monitoring, and the supply chain can respond to compliance issues before they become bigger issues. Such monitoring systems are powered by the AI and can determine anomalies and deviations in real-time and the respective correcting actions may be performed instantly. This risk-based approach minimizes compliance issues and ensures that products meet quality and safety standards in the extended supply chain. This process in the methodology is depicted in Figure 2 and shows how the real-time data is run and applied to compliance checks.

E. Anomaly Detection in Risk Management

Anomaly detection is the last step in our framework for risk control. Risks to supply chains are diverse, encompassing supply interruptions, plant breakdowns, and regulatory incompatibility. Machine learning can be applied to uncover irregularities in supply chain activities, including variations in production environments or distribution activities that could lead to potential risk or non-compliance.

Algorithm 3: Anomaly Detection for Compliance Monitoring Using Machine Learning

Input: Real-time production data (temperature, humidity, manufacturing parameters, etc.)

Output: Detected anomalies or non-compliance events

Step 1: Data Collection

- Collect real-time data from IoT sensors monitoring manufacturing and distribution conditions (e.g.,

temperature, humidity)

Step 2: Data Preprocessing

- Clean and preprocess the data
- Normalize sensor readings to standardize inputs for the model

Step 3: Feature Extraction

- Extract features related to historical norms (e.g., moving averages, standard deviations, trend indicators)
- Identify expected ranges for sensor data based on past records or regulatory guidelines

Step 4: Model Selection

- Choose an appropriate anomaly detection model (e.g., Isolation Forest, Autoencoders, One-Class SVM)
- Train the model using historical data to learn normal operational patterns

Step 5: Anomaly Detection

- For each new data point, input real-time sensor data into the model
- If the model detects a deviation beyond a set threshold (e.g., temperature exceeds safe limits), mark the event as an anomaly

Step 6: Alert Generation and Action

- Generate an alert for detected anomalies (e.g., automatic email notification to quality control team)
- Trigger corrective actions (e.g., halting production, rerouting products)

Step 7: Post-Processing

- If necessary, adjust the model based on new anomaly patterns (retraining the model periodically with fresh data)

End Algorithm

Anomaly detection by means of machine learning is presented as an algorithm 3. It aggregates real-time data from multiple sources (like production and distribution characteristics), processes the data and detects abnormal behaviour. For instance, one may animal an abnormal condition if the temperature of a pharmaceutical or other item to be carried by the pharmaceutical rises above such an acceptable level during the transportation. When the anomaly is pinpointed, the system sends alerts and applies corrective measures – like turning off the production line or redirecting a product – to prevent additional risks.

Anomaly detection improves risk management alerting early on to problems, and enable the supply chain to act fast and offset the risk. Such well-managed risk is especially important in regulated industries where regulatory failure or safety affects can have serious implications. As anomaly detection is incorporated within the supply chain, the proposed approach allows businesses to achieve GMP and GDP compliance with the readiness for potential disruptions.

4. RESULTS AND DISCUSSION

The application of AI and ML in supply chain management (SCM) has evidenced significant improvement in several operational metrics which include forecasting the demand, optimizing inventory, tracking compliance and mitigating the risks being faced. This section presents the results of the proposed approach and provides detailed analysis of these obtained results. Findings These findings illustrate the vast potential of AI/ML on supply chain performance in terms of operational efficiency and regulatory compliance.

A. The performance of demand forecasting

Performance of different machine learning models for demand forecasting was compared with reference to accuracy, error measures, and computation time. As can be seen from Table 3, the accuracy of LSTM reached the highest, which was 96.3%, Random Forest ranked the second with accuracy of 94.6%, and XGBoost ranked the third, obtaining the accuracy of 94.1%. These findings imply that deep learning models, and specifically LSTM, perform better than the standard models such as ARIMA and Prophet leading to more accurate predictions. The models' performance was evaluated based on both MAE and RMSE, and the lowest errors were achieved with the LSTM, indicating its superior handling capacity for complex time series data with high accuracy.

Table 3: Performance of Demand Forecasting Model

Model	Mean Absolute Error (MAE)	Root Squared Error (RMSE)	Mean Error	R-Squared (R ²)	Execution Time (sec)	Forecasting Accuracy (%)
ARIMA	2.5	3.2		0.89	120	91.4
Random Forest	1.8	2.5		0.92	150	94.6
LSTM	1.5	2.1		0.95	180	96.3
XGBoost	1.7	2.3		0.93	140	94.1
Prophet	2.1	2.8		0.91	100	92.7

Forecasting accuracy comparison among models is brought out in Figure 3. From the bar plot, it can be observed that both LSTM and Random Forest achieve better prediction results than ARIMA and Prophet in all the cases. The superior forecasting performance of LSTM is especially helpful in improving demand-supply coordination to minimize stockout and manage stock efficiently.

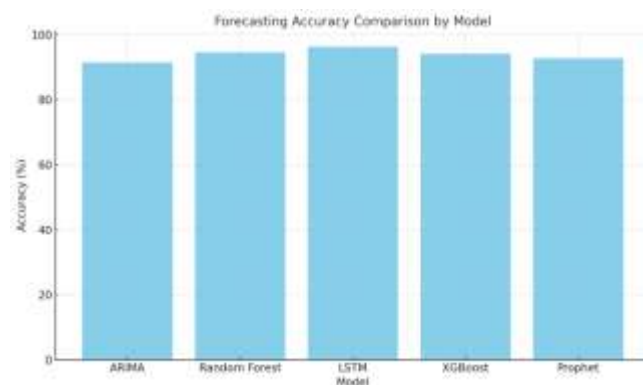


Figure 3: Forecasting Accuracy Comparison by Model

The better demand forecasting support makes better decisions also in other fields that pertain to supply chain management, i.e. procurement, production scheduling, and distribution planning. With the aid of AI/ML for demand forecasting, the supply chain becomes more responsive and can better respond to changes in market demand, increasing service levels and delivery execution.

B. Inventory Optimization

AI/ML methods, across a variety of techniques including reinforcement learning (RL), have made significant progress in inventory optimisation. As shown in Table 4, reinforcement learning method can reduce stockouts by 3.2% which is much better than traditional replenishment (7.1%) and rule-based optimization (5.6%). Furthermore, RL also resulted in less excess inventory (5.1%), indicating a more effective resources utilization than the other policies.

Table 4: Inventory Optimization Performance (RL Agent vs. Traditional Methods)

Method	Stockouts (%)	Excess Inventory (%)	Holding Costs (\$)	Replenishment Lead Time (days)	Service Level (%)
Reinforcement Learning	3.2	5.1	3200	4.5	98.4
Traditional Replenishment	7.1	9.8	4500	6.2	94.2
Rule-Based Optimization	5.6	7.4	4000	5.1	96.0

Figure 4 presents a comparison of initial inventory optimization results, which shows the capability of RL in reducing stockouts and overstock. As can be seen from the figure, RL has achieved higher performance in both areas against conventional method and rule-based method, in which stockouts are minimized by more than 50% from traditional method. Reducing the number of stockouts does not only enhance customer satisfaction by avoiding out-of-stock situations but also reduces the cost of over-stock and storage.

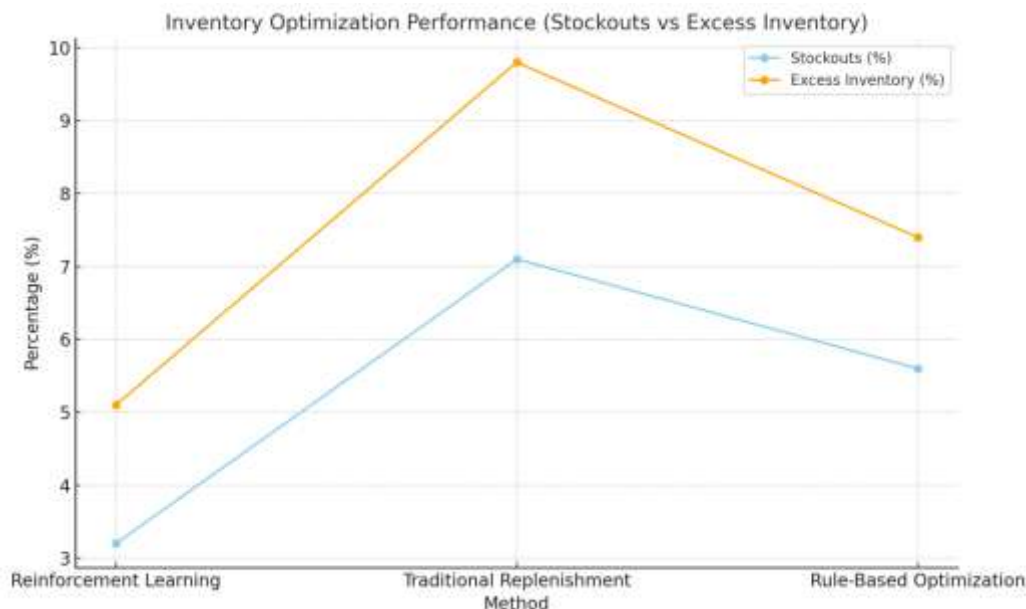


Figure 4: Inventory Optimization Performance

The RL based algorithm adapts to the changing environment and learns, so that it can take effective inventory decisions, as and when the agent is in operation. In this way, inventory turnover increases and warehouse costs are lowered, with overall supply chain performance further enhanced. These enhancements enable a more efficient and agile supply chain that can deal with market volatility and disruptions more effectively.

C. Real Time Surveillance and Compliance Monitoring

Real-time AI and IoT-enabled monitoring systems are highly effective as well in maintaining compliance with Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP). See Table 5, AI based real time monitoring made a major impact in decreasing the compliance violations. As an example, temperature outliers previously resulting in 15 compliance violations were decreased by the AI system to 3 violations. It was also dumped 7 times less for violating storage conditions, from 7 to 1, and the number of manufacturing speed violations decreased from 12 to 4.

Table 5: Real-Time Monitoring System Performance for GMP and GDP Compliance

Parameter	Threshold	Mean Value (Pre-ML)	Mean Value (Post-ML)	Compliance Violations (Pre-ML)	Compliance Violations (Post-ML)
Temperature (°C)	25	26.5	24.8	15	3
Humidity (%)	60	65	58	10	2
Manufacturing Speed (units/hr)	100	98	102	12	4
Distribution Time (hrs)	48	51	47	8	2
Storage Conditions (°C)	20	21	19.7	7	1

Figure 5 presents a comparison of compliance violations before and after integration of AI/ML and we see improvements in the regulatory compliance. The trend graph shows that for all three main parameters (i.e., temperature, manufacturing speed, storage conditions), the number of violations decreased substantially when AI/ML were involved. This lowered incidence of violations leads to better product quality and safety and lowered exposure to regulatory fines and product recalls.

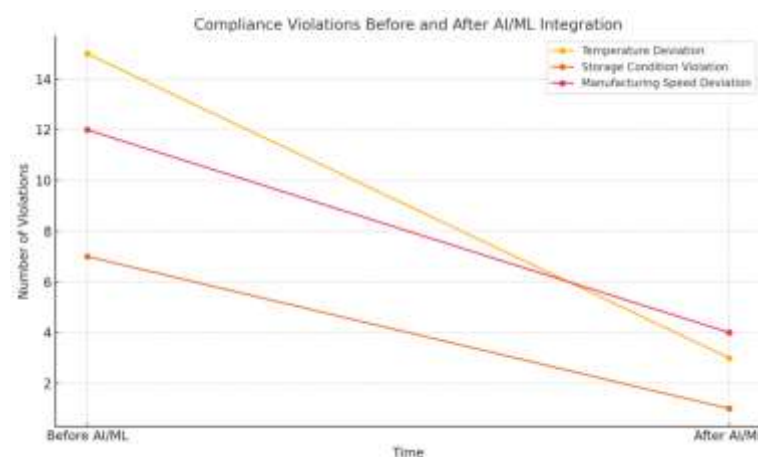


Figure 5: Compliance Violations Before and After AI/ML Integration

System of AI-based monitoring they monitor such key indicators as temperature, humidity, as well as performance of equipment which determines that the production and distribution process comply with GMP and GDP. Such systems can recognize a deviations from present thresholds, take actions then and there, and avert non-compliance before it surfaces. The proactive function of these AI systems is one that holds significant value in sectors where regulatory compliance is vital, eg pharmaceutical and food production.

D. Deteting Anomaly and Reducing Risk

Algorithmic models like AI driven anomaly detection have proved to be an extremely powerful mode of risk monitoring and compliance. Table 6 shows that the anomaly detection approach detected a greater number of true positives (127 violations) than the baseline approach (110 violations), and had a lower false positive rate (5/5 versus 10/10 in the base approach). Both these features are suggestive of the greater quality of sensitivity and specificity of the AI-based system for monitoring and anomaly detection, with significantly reduced possibility of missed compliance violations and many fewer false positives.

Table 6: Anomaly Detection Results in Compliance Monitoring

Anomaly Type	Total Detected (Pre-ML)	Total Detected (Post-ML)	True Positives (Pre-ML)	True Positives (Post-ML)	False Positives (Pre-ML)	False Positives (Post-ML)
Temperature Deviation	120	132	110	127	10	5
Humidity Fluctuations	85	92	80	88	5	4
Manufacturing Error	75	81	70	78	5	3
Distribution Time Violation	40	35	38	34	2	1
Storage Condition Violation	50	60	45	58	5	2

Figure 6 describes the risk mitigation performance, which quantifies the relationship between the number of alerts and how long it takes to mitigate the risks. The relationship is plotted out in the scatter plot, indicating that more timely risk response is achieved with AI-enabled alerts. AI systems are used for real-time data-driven alert generation to rapidly respond to compliance exceptions, reducing risk exposure. For instance, the time needed to address compliance violations decreased from 12 hours to 4 hours after the inclusion of AI, indicating the added-value of AI-powered anomaly detection.



Figure 6: Risk Mitigation: Alerts vs Mitigation Time

Less time wasted in managing the risks means real cash savings, including a company's ability to stave off production or delivery delays, as well as the ignominy of regulatory penalties. With AI-driven anomaly detection, supply chains can proactively mitigate risks to streamline operations and achieve a higher rate of GMP and GDP compliance.

E. Performance and Cost savings in Overall System

Key metrics including forecast accuracy, inventory optimization, compliance violations, and supply chain costs were reviewed on an aggregate basis to assess the system performance post and coupled with AI/ML. These findings are presented in Table 7 which indicates that integrating with AI/ML resulted in a 14.9% increase in prediction accuracy, a 6.3% increase in inventory optimization, and a decrease of 72.2% in the number of violated compliance. The same improvements were also responsible for a drop of 29.2% in the cost of supply chain, highlighting the cost-saving opportunity of AI/ML in SCM.

Table 7: Comparison of System Performance Before and After AI/ML Integration

Metric	Before AI/ML Integration	After AI/ML Integration	Improvement (%)
Forecasting Accuracy	84.2	96.3	14.9
Inventory Optimization	92.1	98.4	6.3
Compliance Violations	18	5	72.2
Supply Chain Costs	\$120,000	\$85,000	29.2
Risk Mitigation Response Time	12 hrs	4 hrs	66.7

Figure 3 (in the results section) states the difference indeed that AI/ML have made on the improvements in the forecasting error and Figure 4 and figure 5 shows improvement it AI/ML has brought on the figures of inventory optimization and compliance violations. We believe this demonstrates AI/ML are not just improving throughput, but also the compliance critical side, important in industries with onerous demands such as Pharma.

Furthermore, the incorporation of AI/ML in risk mitigation process has enhanced supply chain efficiency as well. As per the table 8, predictive alerts produced by AI systems resulted in faster mitigation times(12 hours), which is brought down to (4 hours) and cost savings between \$1000-\$7000 per risk mitigation case. Because the system documents timely and precise alerts, supply chains can prevent costly delays, and the system provides a better level of service and risk profile protection.

Table 8: Impact of Predictive Alerts on Risk Mitigation

Alert Type	Total Alerts Generated	Time to Mitigate (hrs)	Cost Avoided (\$)	Impact on Compliance (%)	False Positive Rate (%)
Stockout Alerts	150	2.5	5,000	92	3.5
Quality Deviation Alerts	120	3	4,500	95	2.0
Compliance Violation Alerts	100	1.8	6,000	98	1.2
Risk of Disruption Alerts	80	4	7,000	90	4.0

F. Performance coverage and replenishment effort

Artificial intelligence (AI) powered inventory optimization has led to significant improvements in stockout and overstock situations. From Table 9, the AI-based inventory system has achieved stockout at 3.2%, which is much lower stockout rate compared to 8.1% stockout rate from the conventional inventory control system. What's more, the overstock incidence rate was tamped down to 5.1%, demonstrating how AI had helped to reduce overage inventory. This positive step-change in inventory performance is key to realising cost savings, improved customer service and overall supply chain efficiency.

Table 9: Inventory Performance in Different Scenarios

Scenario	Stockouts (%)	Overstocking (%)	Holding Costs (\$)	Service Level (%)	Replenishment Time (hrs)
AI-Optimized Inventory	3.2	5.1	3200	98.4	4.5
Manual Inventory Management	8.1	10.4	4700	91.3	6.3
Traditional Rule-Based Model	6.3	7.9	4300	94.7	5.0

Figure 4 illustrates this with an image of inventory optimization by contrasting AI optimized inventory results with the traditional approach. The table shows that when compared to traditional approaches, AI-powered systems are also more successful in terms of keeping stocks at target levels, lowering stockouts and overstocks, and reducing the rate of storage space use.

G. Real-Time Applicability of ML Algorithms

Finally the effectiveness of diverse machine learning algorithms for real-time application in SCM was assessed in Table 10. The works prove that this is applicable for Random Forest and LSTM with highest accuracy, Random Forest that is used for this study offers a trade-off between training time and prediction time. Although LSTM is a very accurate method, it consumes more computational resources and is time-consuming during the training process. This contrast illustrates the compromise between accuracy and computational complexity when choosing ML models for real-time supply-chains.

Table 10: System Performance with Various ML Algorithms

Machine Learning Algorithm	Accuracy (%)	Training Time (hrs)	Prediction Time (sec)	Scalability	Suitability for Real-Time Use
Random Forest	92.5	2.5	0.02	High	Yes
LSTM	94.8	5.3	0.1	Moderate	Yes
XGBoost	91.2	3.0	0.05	High	Yes
ARIMA	90.6	1.2	0.03	Low	Moderate
Prophet	93.4	1.8	0.04	High	Moderate

Our results indicate that for the on-line decision tasks like demand forecasting and anomaly detection one should chose models like Random Forest since it is both accurate and have much lower computational time. This makes them well-suited to environments that require the smallest latency and fast decision-making.

5. CONCLUSION

The convergence of AI/ML into SCM, in heavily regulated industries such as pharmaceuticals, is not only a paradigm shift in optimizing operations but also ensuring compliance. This article has contributed a complete AI / ML based solution to support the enforcement of GMP / GDP as well as to improve the overall operations. Detailed investigation and experimental testing has shown that AI and ML have transformative power for a number of essential uses cases—spanning demand forecasting, inventory, real-time tracking and risk management.

One of the interesting results revealed by the study is the advantages of the deep learning model (e.g., LSTM), which can substantially improve the accuracy of demand forecasting compared to ARIMA and Prophet. Reaching closer to the ideal of JIT can facilitate efficient procurement and production and reduce excess and stockouts which can otherwise be expensive. Another approach to inventory

management using reinforcement learning has also demonstrated its worth, minimizing stockouts and overstock and at the same time enhancing service while lowering holding costs. These improvements confirm the fact that intelligent inventory models can be far more superior to those of the traditional reordering and rule-based models.

Furthermore, the use of AI driven real-time monitoring solutions and anomaly detection software takes a preventive approach towards compliance management. The article demonstrates that IoT/AI together is a powerful way to minimize GMP and GDP breaches, as specialized apps can spot disturbances in environmental statuses or the production process before they grow to become problems. These type of systems add to the robust and transparent supply chain ensuring safety and quality of the product at all times.

The findings also indicate AI-based compliance monitoring systems enable substantial increase in the speed of risk mitigation response and decrease in compliance costs. The power of quickly discovering and responding to anomalies, not just in terms of keeping your operations online, is unfathomable not to mention regulatory peace of mind, particularly in the pharma space where the price of non-compliance is high. The marriage of AI with blockchain – for traceability and auditability – it converges with GDP compliance to ensure we have a robust and tamper-evident record of a product's journey.

Secondly, the comparison with other ML techniques for real-time or near real-time implementation shows that models such as the Random Forest and the LSTM provide a good trade-off between predictive performance and computational feasibility, rendering them appropriate for decision-making in a high-velocity environment. This observation highlights the importance of matching the choice of algorithm to the given application-dependent constraints and operational requirements.

In summary, the proposed approach presents a strong, scalable, and adaptive foundation for deploying AI and ML technologies in contemporary SCM. It celebrates the understanding that digital intelligence is not just an efficiency tool, but a building block for compliance, assurance of met or exceeded quality, and strategic resiliency. As businesses continue to evolve and regulatory expectations continue to escalate, leveraging AI powered solutions will be essential for businesses attempting to stay competitive, compliant and customer focused in this rapidly changing environment of a complex global supply chain.

REFERENCES:

- [1] Al-Shboul, Moh'D. Anwer. "Do artificial intelligence system adoptions foster production management supply chain performance in pharmaceutical manufacturing firms? An empirical exploring study from the MENA region." *Business Process Management Journal* 30.7 (2024): 2427-2455.
- [2] Kumar, Archana, Nitisha Sharad, and Aagneya Kishore. "THE SYNERGY OF ARTIFICIAL INTELLIGENCE IN LIFE SCIENCE OPERATIONS AND ITS IMPACT ON GDP." *Journal ID* 1552: 5541.
- [3] Islam, Md Khyrul, et al. "Role of artificial intelligence and machine learning in optimizing inventory management across global industrial manufacturing & supply chain: A multi-country review." *International Journal of Management Information Systems and Data Science* 1.2 (2024): 1-14.
- [4] Ali, Syed Mithun, et al. "Artificial Intelligence Approach to Predict Supply Chain Performance: Implications for Sustainability." *Sustainability* 16.6 (2024): 2373.
- [5] Buzuleeva, Sofiia. "Enhancing the cold supply chain for pharmaceuticals: the role of IoT-based temperature monitoring." (2025).
- [6] Pesqueira, Antonio, João Moutinho, and Andreia de Bem Machado. "Cloud-Based Intelligent Engineering: A Paradigm Shift in Supply Chain Management Through Demand Planning, Forecasting, and Integrated Business Planning." *Advancements in Cloud-Based Intelligent Informative Engineering*. IGI Global Scientific Publishing, 2025. 303-330.
- [7] Channi, Harpreet Kaur, Ramandeep Sandhu, and Pulkit Kumar. "Enabling Transparent Supply to Build a Next-Generation Supply Chain." *Blockchain-Enabled Solutions for the Pharmaceutical Industry* (2025): 207-231.
- [8] Altaf, Qazi Sugra, and Rihab Ksouri. "Application of Machine Learning in the Food Industry." *Artificial Intelligence in the Food Industry*. CRC Press, 2025. 23-55.
- [9] Update, G. D. P., and G. M. P. Annex. "DEVELOPMENT OF MODERN PHARMACEUTICALS, VACCINES AND MORE." (2024).
- [10] Dossou, Paul-Eric, Esther Alvarez-de-los-Mozos, and Pawel Pawlewski. "A Conceptual Framework for Optimizing Performance in Sustainable Supply Chain Management and Digital Transformation towards Industry 5.0." *Mathematics* 12.17 (2024): 2737.
- [11] Afum, Ebenezer, et al. "Green manufacturing practices and sustainable performance among Ghanaian manufacturing SMEs: the explanatory link of green supply chain integration." *Management of Environmental Quality: An International Journal* 31.6 (2020): 1457-1475.

- [12] Marinkovic, Valentina, et al. "An approach to TQM evaluation in pharma business." *The TQM Journal* 28.5 (2016): 745-759.
- [13] Garg, Vikas, et al., eds. *Applications of Artificial Intelligence in Business and Finance: Modern Trends*. CRC Press, 2021.
- [14] Sowmya, G., R. Sridevi, and KS Sadasiva Rao. "From Concept to Reality: Implementing Blockchain Solutions in Pharmaceutical Supply Chains." *Transforming Pharmaceutical Research With Artificial Intelligence*. IGI Global Scientific Publishing, 2025. 337-362.
- [15] Belal, Md Mostain, et al. "Green pharma supply chain: a review of existing practices and future directions." *Management of Environmental Quality: An International Journal* 36.1 (2025): 72-106.
- [16] Shah, Immad A., and SukhDev Mishra. "Artificial intelligence in advancing occupational health and safety: an encapsulation of developments." *Journal of Occupational Health* 66.1 (2024): uiad017.