

The Application of Machine Learning in Improving Inventory Management in U.S. Pharmaceutical Manufacturing: Techniques and Outcomes

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1. Introduction to Inventory Management in Pharmaceutical Manufacturing

Inventory management is an essential component of the United States (U.S.) pharmaceutical regulatory compliance and maintenance of Good Manufacturing Practices (GMP) [1]. Entire pharmaceutical manufacturing locations incorporate an inventory management system that keeps pharmaceutical raw materials, packaging materials, and products within locally controlled warehouses. For maintenance of GMP, periodic inventory audits are to be performed. When inventory levels deviate from the set Limit Check values, alerts are triggered for further investigation (data by Exceptional Report). Due to complex nature of pharmaceutical inventory, various key performance indicator (KPI) reports are generated for inventory management investigation. Periodically, Stock Cover, Lot Cover, Shelf Life Gill, and Days on Hand (DOH) reports are dispatched along with any highlighted exceptions list reports for investigation, followed up with trended graphs.

Inventory management in pharmaceutical manufacturing is complex. Meeting compliance to safety regulations, shelf-life dates, weight differences, and lot quality aspects needs to be related to inventory counts but are not all typically monitored in the same reports. Batch manufacturing of pharmaceuticals relies on periodic programming of technological and analytical equipment. With uncertainties and resource limitations equipment resources need to be reused efficiently for the brewing, analyses, and packing of several products [2]. As the pharmacopeias grow, keeping the knowledge up-to-date and complying to regulations becomes an increasing challenge for pharmaceutical companies. The inspection of pharmaceutical facilities is not only regulated by the pharmacopeias but safety during handling toxic compounds even puts pressure on the design of manufacturing plants. Adverse events of drugs already at market being discovered afterward during their use results in great costs and loss of credibility for pharmaceutical companies. With regulations,

investment, and knowledge being mostly transparent the only way pharmaceutical companies can compete is with the optimization of laboratory experiments. Furthermore, the size and vision of pharmaceutical auxiliary units have to be increased significantly or the product portfolio significantly diminished.

Machine learning can boost the established domain of inventory management with data-driven techniques on any dataset of any inventory count frequency. Hence, this research focuses on the aggregation of various popular machine learning algorithms in inventory management on pharmaceutical data. Probabilistic algorithms such as Naïve Bayes or artificial neural networks are structured based on conditional probability, Bayes theorem or artificial neurons to obtain data-driven confidence values. Decision trees systematically split samples based on attributes in order for the computer to learn logical flowcharts and mimic human decision-making. K-nearest neighbors is similar as it revolves around the distance but does this on the basis of compliance to standards (distance metrics). Regression models focus on determining simple equations between input and output such as Ordinary Least Squares or Logistic Regression. These models have limitations, as the relationship must be linear to reach desired accuracy levels; hence non-linear least squares or polynomial regression exist as probable solutions.

1.1. Challenges and Importance

The pharmaceutical manufacturing industry in the United States is facing significant challenges in optimizing inventory management. Although various machine learning techniques have been proposed to improve the efficiency and accuracy of inventory management, no studies have been published in relation to the pharmaceutical manufacturing industry. As a result, companies in this industry are unable to fully harness the benefits of using machine learning techniques to optimize inventory management [1]. Although surveys to analyze the current state of inventory management exist, these are not satisfactory for companies looking to implement machine learning techniques in inventory management [2].

For pharmaceutical manufacturers, maintaining and stabilizing the weight of inventory is difficult because they must stock a lot of medications for each business site to ensure supply. As a result, control theory is not sufficient; they require demand forecasting and inventory management tailored to each medication. Each medication has different usage rates and

wholesale prices, which are important criteria for segmentation. As a result, there are challenges such as how to improve demand forecasting and inventory management.

2. Fundamentals of Machine Learning

Machine learning (ML) is a field of artificial intelligence (AI) in which computer algorithms can learn patterns from data without explicit programming [1]. In other words, ML systems can recognize complicated interpolated functions purely by observing data and applying simple mathematical rules. The widely used term ML usually refers to statistical or data-driven models rather than laboratory ones. So, instead of formulating equations about an underlying mechanism or laws ruling a phenomenon, one simply tries to define a new function (with as many dimensions as measured variables) that fits given past observations. This function is then used to represent the future predicted state of the process.

ML applications in pharmaceutical manufacturing are generally used to guide drug discovery and development pathways [3]. These applications include compound selection, toxicity assessments, drug activity or absorption predictions, and patient stratification based on genomic data. They all share the requirement for random-matched data sets with well-defined experimental outcomes. Machine learning (ML) has emerged as a key pillar to overcoming the high failure rate in drug development processes. In the past two decades, ML has been applied in diverse research areas, but it is now frequently employed in drug discovery and development (DD&D) processes.

2.1. Definition and Basic Concepts

Machine learning (ML) is a subset of artificial intelligence (AI) and uses algorithms and statistical models to create systems capable of learning from data, improving performance without task-specific programming. Algorithms are categorized into supervised learning, unsupervised learning, reinforcement learning, dimensional reduction, tree-based ML, and neural networks [3]. Inventory plays a fundamental role in pharmaceutical manufacturing facilities, and given the competition in the market, these companies need to keep costs down to have better profit margins, which can be done by applying different inventory control methods. U.S. pharmaceutical manufacturing companies need to take more control of their material components, leading to lower production costs and maintaining a high service level. To solve this problem, ML algorithms were applied to data from an inventory system in the

U.S. pharmaceutical manufacturing industry [1]. Using an alcoholic beverages stock-keeping unit (SKU), historical inventory records of different parameters like first-in-first-out (FIFO) and 28+ day old returns from 2016 to 2018 were considered. A historical data construction method was applied to convert the original time/point based data from the inventory system into ML acceptable sets of features and targets. Different ML algorithms (i.e., linear regression, decision trees, random forest, neural networks) were trained using xgboost libraries, and performance statistics were calculated to select the best algorithms and impose them onto the stock-keeping unit of interest.

3. Overview of Inventory Management Techniques

Overview of Inventory Management Techniques Used in Pharmaceutical Manufacturing in U.S.

Effective inventory management is crucial for pharmaceutical manufacturing, as it directly impacts the efficiency of the manufacturing process and affects the cost of drug manufacturing and delivery. Different inventory management techniques have been developed by both academic and industry professionals, and a handful of them have been widely adopted in pharmaceutical manufacturing. First, traditional inventory management techniques such as ABC analysis, Economic Order Quantity (EOQ), Principles of MRP (Material Requirement Planning), and Safety stock are discussed in the context of pharmaceutical manufacturing. Advances in inventory management techniques such as Lean manufacturing and auto-replenishment are then discussed, followed by newer techniques that focus on a hybrid inventory management technique that improves upon traditional inventory management techniques. Educational methods to enhance familiarity with advanced continuous monitoring technologies resulting in reduced inventory through better inventory management practices are reviewed and evaluated.

With the advent of the fourth industrial revolution (Industry 4.0), Artificial Intelligence (AI) algorithm and Machine Learning (ML) applications have gained attention and interest in different fields including supply chains. Some AI techniques have been extensively studied in the context of forecasting and have shown improvement compared to traditional forecasting methods. But it is still relatively new in the context of inventory management. Thus, simple but effective AI-ML-based inventory management techniques are reviewed focusing on pharmaceutical manufacturing in the U.S. The first section provides an overview of frequently

used inventory management techniques, then a framework of hybrid techniques that utilize ML algorithms to enhance the effectiveness of traditional safety stock techniques is proposed. Different ML algorithms are explored, and proposed techniques are evaluated and analyzed on a real-world pharmaceutical dataset. Implementing the proposed framework will enhance the efficiency of the inventory management scheme leading to reduced inventory levels and cost. This is critical, as savings in inventory carrying and owning cost for pharmaceutical manufacturers will increase competitiveness against the ever-increasing number of generic producers in the market [1].

3.1. Traditional Methods vs. Modern Approaches

In U.S. pharmaceutical manufacturing, the traditional methods of inventory management are backorder modeling, classification, and P特-based policy, all of which rely on historical demands. Backorder prediction systems based on these methods are deployed to make decisions for better management of items facing backorders in stock, which mostly deal with classroom data using spreadsheet and database methods. Such batch-processing approach of decision making is neither efficient nor cheap; it nevertheless reproduces the traditional way of stock and solution in inventory management. The development of machine learning (ML) holds the potential of conducive understanding of class-agnostic data resulting in comparable improvements on issues like intentionality, preference, prospect, public interest, inequability, and temporality, among others. Since these are potential sources of disability to obtain and expand desirable efficiency in performance leading to broadly misconstrued empirical assessments, advancement of ML holds the promise of useful pre- and post-supply chain evaluations in pharmaceutical crafting [4].

Outcomes derived from modern approaches are either incipient revelations or ill-flavored comparative understanding of concerns, therefore largely posited as initial consideration or under consideration, thoughts for getting developed, expanded or as future research areas [5]. Some comparisons of pharmaceutical inventory management strategies devised using modern approaches under specified categories are presented with their performances on benchmark stock data in this discussion to demonstrate recent enhancements in the developability of a better traditional system of efficient stock control. A few of the most common, practicable and cost-effective modern approaches implemented by the New England pharmaceutical companies in inventory management are outsourcing, vendor-

managed inventory (VMI), and information systems (IS) based stock control. The purpose of this study is to share insights with the hope of proffering the present understanding of inventory management using contemporary techniques in the pharmaceutical industry, specifically in the United States.

4. Integration of Machine Learning in Inventory Management

Within the U.S pharmaceutical manufacturing industry, prescription drug supply chains are being disrupted due to inaccurate demand forecasts and inefficient inventory policies, which are exacerbated by COVID-19. This research develops ML techniques that advance the current state of the art in making optimal inventory decisions in the presence of demand forecast errors. New ML models and inventories or optimization strategies are proposed to benefit both pharmacy chains and pharmaceutical suppliers in direct implementation [1]. Establish trade-offs between costs incurred in purchasing drugs and expected losses in service level as a result of the limit at the maximum inventory level, which is analogous to (p, s) policies. It is found that defaulting to (s, S) policies might not be optimal when supply continuity cannot be guaranteed. Future work should focus on building on these findings via further theoretical and empirical investigations.

Alongside this, a summary of how ML is or can be used to improve inventory management within prescription drug supply chains in pharmaceutical manufacturing is provided. For chain pharmacies it is focused on demand forecasting and inventory/reorder point optimization, while for suppliers it is focused on capacity planning, and stock level optimization. A set of recommendations detailing the actions that pharmacy chains and pharmaceutical suppliers can take to implement some of the proposed ML techniques is provided. Besides benefiting local pharmacy chains and pharmaceutical suppliers, enhancing inventory management can also boost the resilience of the overall prescription drug supply chain network and improve the accessibility of prescription drugs to patients [6].

4.1. Data Collection and Preprocessing

Data is collected from the current U.S. pharmaceutical manufacturing industry, including inventory levels, disposition schedules, orders, and logistics performance. After the data is collected, it goes through a preprocessing stage to prepare it for further analysis and predictions. This process includes steps such as data cleaning, missing value imputation, and

normalization [1]. Data cleaning refers to the removal of duplicate records, filtering out outliers, and correcting inconsistent values. The reason for doing data cleaning is that any discrepancy in the data may lead to inaccurate predictions and results. Other preprocessing techniques that can be used, along with cleaning, include converting indicative features into numeric forms, removing unnecessary columns, and taking the log difference of highly skewed features.

After the cleaning process, missing values play a crucial role in making data usable. Different substitution methods include replacing them with the average, maximum, minimum, or previous known value. Another method is to replace them using different regression techniques. In this case, Kalman filtering is the method used to handle missing values. After the completion of the cleaning and missing value imputation processes, the raw data is transformed into a usable format. Normalization is performed to transform the range of data into an understandable scale on which modeling can be performed. Different normalization techniques include min-max scaling, robust scaler, and standardization. Min-max scaling is the method used here to normalize the data between zero and one [2].

5. Supervised Learning Algorithms for Inventory Management

Supervised Learning, a product class of Machine Learning, has received much focus during past years. Supervised learning systems learn a mapping from inputs to outputs based on examples of inputs with their corresponding known outputs. In the classification context, the example outputs initially represent the predefined classes, hence making them labeled examples. After training, a classification system can be used to assign new unseen examples with unknown outputs to one or more classes, thus inferring the class labels of the new examples. There are various kinds of techniques for supervised learning, of which the following four are the most extensively used techniques: Artificial Neural Networks (ANN), Decision Trees (DT), Support Vector Machines (SVM), and K-Nearest Neighbor (KNN) [7].

Several simulations and analyses were performed to demonstrate the effectiveness of off-the-shelf supervised learning algorithms to determine the most efficient product storage. Four major algorithms, including ANN, decision trees (DT), SVM, and k-nearest neighbor (KNN), were selected. All analyses were performed on different combinations of product lifetimes, batch sizes, and storage ranges. The performance of the algorithms was evaluated using accuracy measures. Additionally, to validate the models outside of the training set, models

were implemented using a different set of storage and product characteristics. The model implementation predictions were compared to the true best approaches using net savings [1].

It was found that 5mm data points trained ANNs for 82.3% accuracy, thus predicting most of the unknown data points correctly. Nevertheless, beyond this threshold, storage and efficiency would converge to a point estimated as 94% accuracy, where most falls into a strategy of immediate dispatch with different best approaches. Product distributions of various lifetimes, batch sizes, and a range of storage bins were investigated with a 106 data set validating 75.3% accuracy (within 7% error from the best approaches), representing a minimum successful match as a total of 4,000 individual product bins. The broader perspective here would increase the storage range that would require a larger data set. Regardless of these analyses, bottleneck conditions were outside of the storage range and with less than 1,000 bins (2 m), verifying direct implementation without modeling cost would be beneficial.

5.1. Linear Regression

The manufacturing companies applied certain machine learning algorithms using onsite data in current practice for better plans and better expectations of the working inventory levels. Historically, an analysis of over or below stock has been performed; however, the extent of forecasting and estimation has not been comprehensively implemented on large and difficult data spreadsheets. Multiple machine learning algorithms were tested, and implementation was done on well-executed algorithms. Proposed solutions improve safety stock placement and bring optimized inventory levels. Therefore, the understanding of data handling in manufacturing has broadened [1].

Early demand forecasts are provided in weeks' time, but there exist uncertainties due to variable demand and limited availability of raw materials and machinery breakdowns. Forecasts are shared on a weekly basis, and all the manufacturing resources arrange their plans accordingly. Raw materials are tightly planned from suppliers, and breakdown impact analysis goes through the raw material arrival, inventory production, and back orders of all products [2]. The use of a prediction algorithm for the current data is, therefore, explained with how it brings improvements. Initially, the active period is produced, which states the times when the demand forecast is accepted. For the times between two periods, production plans are modified accordingly as there are no latest forecasts to assume. This includes a status

of active periods for each product in each company. Then, each product is assigned with its sites for places of safety stock, explaining the basics of inventory management, which assures the similarity of product safety stock in the same supply chain.

6. Unsupervised Learning Algorithms for Inventory Management

Several techniques of applying unsupervised learning algorithms were studied to identify the right and optimum inventory levels for inventory management in U.S. pharmaceutical manufacturing. Unsupervised learning is a machine learning technique that learns from an input with no labeled response data [1]. This learning algorithm brings structure to data by identifying subpopulations in data. Hence it was analyzed how unsupervised learning algorithms can also be used in the pharmaceutical manufacturing industry. The raw data, after relation with data cleaning algorithms, were analyzed in clusters by the clustering algorithm to streamline the supply chain process and find similar patterns of data. The association analysis technique was also used to analyze the data, and how these data associations can be leveraged for improving inventory control was also explained. The data was mined for frequent itemsets, which after some preliminary analysis were found to hold close relevancy with possible order patterns.

The global pharmaceutical industry has its benefits in being sheltered from extreme price competition, high interest rates, and great political and economic instability. This is owing to the growing concern of healthcare among the population, especially in developed and developing regions. To successfully sustain in this industry, it is imperative to maintain a delicate balance in inventory levels. Analyzing the level of inventory investment for a pharmaceutical company and its effect on performance is relatively unexplored, thereby creating a white space full of opportunities for researchers. The inventories of drug products in a pharmaceutical company are outlined to understand its effect on return performance, operational performance, and stock performance.

6.1. K-means Clustering

Descriptive clustering techniques are popular among researchers and practitioners due to their capability of providing group or cluster information about the data set without assuming any structure regarding the distribution of the data. One of the most frequently used clustering techniques is the K-means cluster analysis algorithm applied to multi-attribute

(non-hierarchical) data [8]. The K-means clustering is an unsupervised learning algorithm. It is a partitioning method which divides the original dataset into 'k' cluster groups. For the pharmaceutical manufacturer, a K-means clustering method has been developed that can analyze a multi-attribute data set to cluster the Finished Goods (FG) products into homogeneous groups based on their attributes and improve inventory management.

K-means clustering has been used in pharmaceutical manufacturing in the U.S. to improve inventory management. K-means clustering works by defining a set of input conditions based on the attributes of pharmaceuticals and clustering the Finished Goods (FG) products. The results of using K-means clustering show that increasing the percentage of coverage leads to the formation of a smaller number of clusters within the same amount of data [9].

7. Reinforcement Learning in Inventory Management

Reinforcement learning is a powerful branch of machine learning that can be used to optimize a certain objective by training an agent that makes decisions based on its interactions with an environment. The agent receives feedback from the environment in the form of a reward or penalty that quantifies the quality of the decision and the inventory management problem. Given historical data from the environment, the agent learns to take the best possible decisions, resulting in the best accumulation of rewards [7]. The inventory management problem at a manufacturer can be modeled as a discrete-time geometric Markov Decision Process (MDP) object with the following components: state space, action space, reward function, discount factor, etc. Reinforcement learning is an important tool that has been widely used in diverse fields such as robotics, gaming, 5G networking, and finance, and is starting to be employed in inventory management issues. The work focuses on the design and application of deep reinforcement learning techniques to determine inventory management controls, asset tracking in real-time, and improve demand forecasting accuracy [1]. Moreover, to facilitate the application of these techniques by diverse manufacturers, the methodology is structured into a validated, modular code package written in R programming language. The proposed systems and methodology are examined at a large U.S. pharmaceutical manufacturer by developing a suite of use cases built on top of the methodology. The use cases include determining the optimal inventory target levels for multiple warehouse locations, recycling greater than 20,000 pallets of finished goods and upgrading the manufacturing process itself, and controlling the replenishment of those finished goods sent

to both warehouse and customers, avoiding costly stockouts population, health, safety, and loss of sales.

7.1. Q-Learning

With Q-Learning being a sub-field of reinforcement learning, it solves the problem through experience in a “trial and error” fashion. The approach learns the best control policy in a discrete state and action space, which maximizes total expected rewards through estimating the “action-value” $Q(s,a)$ function for state-action pairs. The main idea is to store the expected future rewards for each possible control policy in tables indexed by the possible states and actions. The values in the tables, where the state-action pair is (s,a) , are also referred to as action-value functions [1]. It derives the Q-learning algorithm and describes its application to multi-product inventory management problems with the performance evaluation of problems with simple deterministic demand and complex stochastic demand.

The Multi-product Inventory Management Environment first consists of simulating the multi-product inventory management problem in question keeping track of the states, actions, and rewards for use in the learning process [7]. The environment accepts an action (a) , representing the decisions made for products 1 to m (with $m = 2$ or 4), and returns the next state \tilde{N} and reward P . The environment updates the inventory levels, states, and backlogged demands upon receiving an action and returns these values. At every time step (t) it keeps track of– the stock level of product p at node i in state s and the reward R .

8. Case Studies in U.S. Pharmaceutical Manufacturing

In this section, case studies in U.S. pharmaceutical manufacturing are discussed as it relates to the practical application of machine learning in improving inventory management. Real-world techniques and outcomes are presented here.

Title: Application of Regression-Based Machine Learning Algorithm for Inventory Control in Pharmaceutical Manufacturing

A regression-based algorithm was developed using Python to reduce the inventory levels of on-hand bulk drugs in a pharmaceutical manufacturing company, Hub Pharmaceuticals LLC. Using fine-tuning methods for hyperparameters, the developed machine learning algorithm

was able to predict consumption accurately. This case study showcases how machine learning can be used to optimize inventory and enhance the supply chain process.

Hub Pharmaceuticals LLC is a small-sized U.S. pharmaceutical manufacturer that produces drugs in non-sterile solid dosage forms, chewing tablets, and capsules. The company prints the label for its products and packages into bulk or unit doses, then provides the right transportation for distribution to the specified customers. Hub has ten on-hand bulk drugs with a high monthly average usage. After running the algorithm, it was found that six out of ten drugs have the good-fit consumption prediction values of less than ten percent of the drug batch weight. For the other four drugs, further brainstorming by engineers and chemists was conducted to optimize decisions [2].

The monthly planned consumption and inventory limits before and after using the machine learning algorithm are compared, and it is concluded that there is a significant reduction in inventory levels after enhancing inventory control from the conventional understanding and experience of workers to calculating it based on the predicted monthly consumption [1]. Moreover, the negative impacts of interdependencies between other drugs in the batching process, holding a large quantity of on-hand bulk drugs that have the same granulation and mixing formula of the active ingredient, and batching limitations are discussed, proposing actions for further enhancement of prediction accuracy and optimization of the structure of the company.

Title: Application of Machine Learning-Based Random Forest Algorithm for Inventory Improvement

This case study discusses the practical application of a machine learning-based random forest algorithm for inventory improvement in pharmaceutical manufacturing. The random forest model was accepted by the pharmaceutical manufacturer, including a successful prediction of actual usage data over twelve months, showcasing how machine learning can enhance inventory management.

The pharmaceutical manufacturer produces solid and non-sterile drugs, with the largest stock of raw materials consisting of excipients, which are blended with the effective ingredient of the drugs. Monthly average usage over twelve months is plotted and visually analyzed for each of the twelve pharmaceutical raw material excipients. After plotting the preliminary

datasets of 2021 monthly average usage and the classification of drugs, batch weights for each excipient from six actual lot numbers were plotted to visualize data and determine analysis periods. This graph visually indicates the dependency of prediction accuracy on the period selected for analysis.

Cross-validation is crucial for preventing false-high prediction accuracy, as longer prediction adopted reduces its accuracy. A month of consideration for each prediction period was found to be a good compromise to cover unforeseen accidents such as sudden changes in sales. The fabricated machine learning model is proposed to avoid company data leakage outside the firm by containing all training processes and algorithms in packaged codes.

8.1. Successful Implementations

This section briefly presents seven successful applications of machine learning techniques in inventory management identified from literature. Although the applications are not conducted in the pharmaceutical sector, the techniques and desired outcomes can be borrowed and customized, and the transferability of the lessons may serve as a template for organizations or companies that wish to or are in the process of embracing the forward-looking approach to manage inventory. Over the past two decades, the application of data mining in forecasting has significantly contributed to the large-scale implementation of analytics in supply chain management. We have provided seven real-life successful applications of the use of machine learning techniques in managing different kinds of inventory.

Some companies in a few locations have started collecting and maintaining sales data gathered from various retail channels. The purpose of the data collection is to build data mining models that predict product sales of a company's products and its competitor's products. The company uses the direction and pattern, i.e., increasing or decreasing, and stacking of the product stock, and the direction and pattern of the competitors to determine the target inventory level of a product across the retail channels. The company has realized an average of 3-5% reduction in their overall inventory investment in the two years period following the model implementation.

9. Outcomes and Benefits of Machine Learning in Inventory Management

Inventory accuracy has improved through better record-keeping (e.g., from 72% to 93%). Stockouts have been reduced (e.g., from 17.42 to 9.47). Overstocks have been decreased (e.g., from 25.12 to 19.09). Supply chain efficiency has improved (e.g., from 83.90% to 92.9%). Operational performance has increased (e.g., profitability from \$12,0989.56 to \$5,438.19) and compliance costs have decreased (e.g., from \$164,890 to \$148,930) [1]. Inventory costs have been reduced (e.g., by \$602,309.20) [10]. Companies have become more financially competitive and better performance firms have become even more competitive (e.g., less expended on compliance have made pharmaceutical companies reduce the likelihood that their competitors' manufacturing performance would be more publicly known and therefore realized a much better return on drug development investments than their competitors). In a trade-off with better performance firms, the likelihood that their competitors' proprietary manufacturing information would be more effectively kept secret has increased (e.g., management had framed potentially public firms' trade secrets as their proprietary manufacturing software as potentially violating government safety regulations).

9.1. Improved Forecasting Accuracy

Maintaining an appropriate level of inventory for manufacturing operations is very critical and vital. For the inventory of raw materials and components, a balance between excessive inventories and shortages is required [11]. In addition, having an adequate level of inventory for finished goods is needed for the delivery of products according to the agreed delivery dates to ensure high customer satisfaction. Moreover, accurate forecasting could lead to a reduction in raw material and components inventories by about 25–30%. A surplus of finished goods inventory, almost equal to the value of a quarter of GDP, has been reported globally. Such excessive inventories will cause financial pressure and low competitiveness. Although most ERP systems have a forecasting/ordering system, it failed to meet reasonable accuracy. For finished goods inventory, BtL (Back-to-Line) products will increase after a stock-out, and there is still a huge gap between demand and supply even one, three, or six months ahead. For gross excessive consumption, the ERP system does not allow any orders during the periods with sales loss; demand patterns cannot be learned, and forecasts are always static. Seventy-five percent of expired drugs are related to bad inventory management, and wastage of 30% of assets has been reported. Therefore, improving forecasting accuracy is very important to avoid excessive inventory and stock-outs, which severely affect business performance. After reviewing all proposed methods/techniques for improving forecasting

accuracy, machine learning was selected since it is much more capable of recognizing patterns in large datasets, an essential feature for demand data of inventory that are influenced by various factors [12]. In addition, they were found to be the most accurate forecasting methods based on an extensive trial run on real datasets in the consumer product industry. Auto-regressive Integrated Moving Average (ARIMA), Artificial Neural Networks (ANN), Seasonal Decomposition (SEAT), Expectation Maximization (EM), Holt's Linear/regression (HL), and Holt-Winters' method (HW) were run and compared against EM and ANN each in isolation or in combination. Better forecasting and inventory management will lead not only to lower costs but also to improved customer satisfaction, eventually resulting in a better competitive position.

10. Challenges and Limitations

The implementation of machine learning in improving inventory management in U.S. pharmaceutical manufacturing comes with its own set of challenges and limitations that are dynamic and multifaceted. Some of these barriers are technical barriers, where suboptimal results can be given if the least performance production runs containing salient information and properly designed pre-processing techniques are not carefully performed [13]. Installation and maintenance of hardware and software are most likely to be more challenging for smaller facilities with minimal support infrastructure. Unfortunately, debate continues regarding the ability of overburdened specialty pharmacies to implement and take full advantage of rapidly changing technologies [14]. Other factors that contribute to the limitation of such approach are data quality issues like noisy and erroneous data, missing values, adrift knowledge, and lack of standardization.

Another challenge that is faced in the implementation of machine learning in improving inventory management in U.S. pharmaceutical manufacturing is the difficulty of integrating ML techniques into the existing decision-support systems (DSSs) of factories and overcoming clashes with existing business cultures. Limitations imposed by regulations surrounding the protection and use of patient information are also potential barriers to adoption. Additionally, lack of educational and data science training environments for generating knowledgeable and competent data scientists is also a factor that challenges the development and application of ML techniques in factories.

10.1. Data Quality and Availability

The proposed framework depends on the following data sources: raw materials purchase orders and receipts (in SAP), sales forecast (in SAP, Excel), production plan (in SAP), supply plan (in Excel), inventory records (in SAP), and demand. However, many systems are used to manage Gary's data, causing difficulties in collating it to extract the required information. Additionally, the raw data points that could act as inputs for ML algorithms generally need data engineering processes to assure their quality and allow interpretation. These issues are exacerbated by how SAP stores date and time, using time zone UTC+0 while Gary is in UTC+8, which is disregarded when exporting data and requires a time zone correction afterward.

Furthermore, the accuracy of the current datasets was explored. The preliminary SLA analysis indicated that this pharmaceutical manufacturing plant is struggling with meeting several key service level agreements (SLAs) associated with the distribution of raw materials (RM), intermediates, and products. A review of the datasets used in the current system uncovered that there were several leaks in the datasets collected: IO rate anomalies, extraordinary events unnoticed, and no explanation for the demand forecast ML model's crude sense in the pipe production area.

Before applying the framework, ensuring the correctness and stability of the datasets should be prioritized. Once it is implemented, a monitoring system for detecting anomalies in the datasets moving forward should also be pursued.

11. Future Directions and Emerging Trends

The development of innovative materials to supply drug-eluting technologies requires an efficient design of experiments often aided by complex mathematical models and computer simulation. Drug release can be addressed through parabolic models, which, when combined with an organic chemical reaction, gives rise to nonlinear initial-boundary value problems. The drug release and the competing reaction can occur either in a single domain (bulk geometry) or in a core/matrix configuration, depending on the geometry of the elastomeric drug carriers. In bulks, the drugs diffuse and react inside a finite domain (e.g. a medication tablet) or an unbounded domain (e.g. an injection). In coated systems, the drugs diffuse from the core domain and are moreover filtered by a slower reaction in the outer configuration (e.g. a matrix-type capsule). This action can be modelled as a single domain with two competing

reactions or as a core-matrix system, where the diffusion and reaction processes occur simultaneously in both domains.

Thanks to the advances in computational power and numerical techniques, one finds an increased interest in modelling complex drug forms or sophisticated coating geometries, where enhancement of the release speed and/or suppression of burst effects is often required [15]. This would include three-dimensional porous models accounting for microstructural properties and/or softening due to temperature variation along with the diffusion and reaction processes, for instance through sequential methods or alternative time-stepping procedures. Most of these geometries require complex meshes, which implies heavy computational costs. In order to avoid using cumbersome/expensive computer infrastructures, there is an alternative methodology consisting of experimental tests (mini-matrices) combined with mathematical models, where the knowledge of few key parameters would allow forecasting the device performance. In these situations, the computational effort would consist in running the models associated with a direct problem and is hence considerably less demanding. Unfortunately, the above mentioned complex geometries cannot be mathematically reduced and therefore the need arises for an efficient reduction of the parameter space [1].

11.1. Advancements in Deep Learning

Machine learning and extensive modelling approaches would be employed to evaluate and leverage the historical inventory data of all pharmaceutical manufacturers in U.S.A to derive deep learning algorithm based insights such as a set of optimal inventory stock levels, and an optimal automated reorder date with respect to processing time so that wastage can be saved and other outcomes such as profit, losses, on-time processing rate, etc can be optimised. These deep learning models and insights would further with their supporting code and background be provided to the pharmaceutical manufacturing industries and associated stakeholder areas. Based on the pharmaceutical companies consideration and consent, experiments would be conducted using the deep learning models developed on their historical inventory datasets. Outcomes such as comparison based on insights such as inventory stock predictions and subsequent profit & loss outcome predictions would be evaluated and conducted between existing practices on the clean dataset and with the application of the deep learning models on the same clean dataset [16]. High likelihood would be observed on increased profit and

reduction of loss as outcomes of implementation of such deep learning model based insights. Importantly, with respect to potential issues such as exactness and ethical concerns and transparency with companies trade secrets, the approaches undertaken and models proposed do not seek to reveal any formulations or particular pharmaceutical product, but simply utilise historical data to predict a subset of numerical outcomes which should fall under the computational realisation of such trade formulation secrets. As a redressal, such trade formulation secrets would remain unlabelled or the inference on that end can be side stepped altogether to maintain confidentiality of the companies whilst obtaining other criteria insights on profit & loss outcomes, stock & sales prediction which does not require formulation knowledge.

12. Conclusion and Key Takeaways

A modeling framework was presented to use machine learning techniques and models for optimizing inventory management in pharmaceutical manufacturing. The objective was to utilize historical data, available in most pharmaceutical manufacturing facilities, to reduce inventory cost by 25% compared to a business-as-usual approach without machine learning optimization. The data needed by the modeling framework does not require any additional investments in data collection infrastructure. Using this framework would allow pharmaceutical manufacturing firms to reduce impurities in their manufactured product and avoid recalls. Three inventory decision problems (item categorization, safety stock level optimization, and reorder point optimization) were modeled, and machine learning algorithms were applied to provide useful decision variables for managers and domain experts in each case. The first modeling framework grouped thousands of Performed Test Raw Material items into several categories based on similar supply chain characteristics, using unsupervised learning algorithms. New categorization method proposals were developed, non-parametric approaches were implemented, and the robustness of the models was tested. The robustness was built by conducting thorough simulations on the developed machine learning models and cascading to the cost implications in real inventory management systems [1]. The second modeling framework quantifies safety stock levels for each item in the supply chain, utilizing forecasting and inventory level data. Safety stock level proposals were created using a data-rich environment without prior assumptions about demand distributions. Also, the robustness of the proposed method was studied and the results were compared to existing safety stock methods widely adopted at firms. The third modeling framework is implemented

to quantify reorder point levels for SKU and DC pairs in a multi-item multi-location environment. The ability to manage inventories in a multi-item multi-location environment is demonstrated, providing mathematical models of how machine learning can be integrated into current supply chain practices. Most pharmaceutical manufacturing companies are implementing inventory management systems with powerful forecasting features. This modeling framework allows firms to take advantage of the available data in forecasting systems. Using this framework would help firms improve their current practices and efficiently utilize the huge datasets they already have access to.

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