The Role of AI-Driven Predictive Maintenance in Reducing Downtime in American Medicine Manufacturing

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1. Introduction

The role of AI-driven predictive maintenance in reducing downtime in American medicine manufacturing is an important research topic and is the subject of this essay. Manufacturing is a complex process that relies on many activities and functions. Over time, processes of discrete and continuous functions will become outdated and less efficient. A breakdown of machinery and equipment can result in major disruption and loss of productivity, impacting a company's bottom line. Large international organizations have invested millions in the upkeep of machinery and equipment. Proper maintenance is strategically needed to continue efficiency, reliability, and satisfactory performance. Downtime in manufacturing needs to be minimized. Advancements in artificial intelligence (AI) present possibilities for process and work automation, accuracy improvement, increased productivity, and understanding human behavior. AI has the potential to positively impact operating procedures that can significantly reduce downtime associated with the malfunction of machinery and equipment. A better understanding of how AI can mitigate and understand causes of downtime is needed. The background, purpose, and scope of the research topic are presented first. It provides context on the growing use of AI-based predictive maintenance systems in manufacturing organizations and outlines why it is important and how this need can be met. The significance of the issue is elaborated on in the motivation section and aims to raise curiosity about the topic. Predictive maintenance is introduced and the potential role and contribution of predictive maintenance to downtime are stated in terms of concerns about downtime and how this topic needs to be better understood. Finally, the methodology section presents an overview of the essay and the methods used in approaching the research topic.

1.1. Background and Significance

As American medicine manufacturing plays an essential role in the nation’s health care by providing the necessary compounded sterile preparations, the failure of its systems may incur not only huge sums of money in repair and service costs for the companies but may also dangerously affect the health and lives of many patients waiting for medications. Therefore, preventing, or at least reducing, the odds of such events is of utmost importance. This is where a very different and promising solution to common maintenance problems is proposed — AI-driven predictive maintenance (PM) systems. Supported by artificial intelligence (AI) and so-called "smart" devices, the new approach will use real-time digital information collected from the production machines with various sensors. The instantly gathered data then would be transferred to cloud or local storage where further processes would be performed by machine learning (ML) algorithms [1]. With time these algorithms are expected to detect and indicate any emerging issues of damaged machine components and propose actions to avoid failure prior to the breakdown.

Real-time changes in the monitored machinery would be analyzed in order to establish specific patterns of "healthy" device behavior. After implementing the necessary adjustments such as removing outliers, smoothing noisy signals, modifying sampling rates, and fulfilling data for computing set technical variables with the help of pre-processing tools, the collected information would enter the so-called prediction block. Here standardized analytical techniques, including mainly signal processing methods, statistical models, and ML algorithms, would be employed to uncover hidden patterns in the data. Some developed models would be able to predict or forecast future machine condition whereas other would check the current state of production devices (either equipment health monitoring or fault detection and diagnostics). All these actions would be done in near-real-time, saving the manufacturing process valuables, such as utilities and workforce salary [2].

1.2. Purpose of the Study

The purpose of this study is to create a comprehensive overview of AI-driven predictive maintenance and its role in reducing downtime. There are many preventive maintenance instruments, both recently developed and those already established in management practice. However, there are questions of how AI-driven predictive maintenance can reduce downtime in medicine manufacturing in America? Why is AI-driven predictive maintenance the best solution and approach to adopt in industries? Furthermore, what influences the efficacy level of AI-driven predictive maintenance observing at the industry as a whole?

To obtain these aims and hopes, a number of objectives shall be pursued through the paper: to elucidate how AI-driven predictive maintenance reduces downtime, to clarify why it is the best preventive maintenance approach, and to determine what external influences and internal conditions dictate the success of AI-driven predictive maintenance implementation in minimizing downtime. Questions and clarifications shall be observed at the level of industry within American medicine manufacturing. Social and economic theories shall be deployed assessing the attributes of those industries. Modeling the situation on a theoretical plane will generate suggestions or advice for the doctor business on the practical plane [1].

1.3. Scope and Limitations

Such a complex topic includes many aspects and data that should be involved in the research. Therefore, in order to achieve reliable, credible and complete results, the following restrictions will apply:

1. This research will only focus on U.S. companies operating in the field of medicine manufacturing. Janssen Pharmaceuticals, Genentech, Pfizer, Merck, Bristol Myers Squibb are some of the largest medicine manufacturers operating on U.S. territory, that can be further analyzed. 2. Such diseases as Multiple Sclerosis, Cardiovascular Diseases, Alzheimer's, Lupus, Sickle Cell Anemia will be taken into consideration. 3. Currently, available smart technologies and approaches to predictive maintenance will be thoroughly researched, but future suggestions will be given only for AI predictive maintenance. 4. Only qualitative approaches to data collection will be applied: interview with a credible expert and analysis of secondary qualitative data (e.g. medical journals, technology reviews, news articles). 5. Collected expert's personal thoughts and suggestions will not be presented nor be discussed in such a rich detail, but will rather be generalized, in order to maintain expert's privacy and comply with ethical standards. 6. Such terms as "health care," "health industry," "health services," "medicine," "pharmaceuticals" will be seen as direct synonyms.

2. Overview of Predictive Maintenance

Predictive Maintenance (PdM) is a maintenance strategy that aims to make the best use of maintenance resources according to the condition and performance of equipment. It utilizes sensors, measurement devices, and data processing to monitor equipment in real-time [3]. This strategy allows for more informed and accurate maintenance planning, prior to a critical failure, as opposed to traditional time-based and run-to-failure strategies. The data of rotating machinery can detect single point failures caused by excessive loading or wear of a component and thus allows for targeted component replacement rather than the whole machine. It also monitors performance changes, such as failing lubrication or blocking of filters, leading to efficiency losses, and allowing for component cleaning or service before excessive efficiency losses occur. Furthermore, it enables improved understanding of the background process leading to machinery failure and thus helps to make effective investments in e.g. training or replacement of faulty equipment.

Implementation of predictive maintenance results in several benefits. It considerably improves cost efficiency over other maintenance strategies; after implementation, maintenance is carried out only on demand instead of on set schedules, thus the costs of over-maintenance with no significant quality improvement are avoided. Additionally, the risk of unplanned breakdowns and disruptions of the production process is reduced, leading to an increase in equipment availability and controllability of production. Unplanned downtime can be especially costly in continuous production environments such as oil refining, energy production, or food processing [4]. Implementing predictive maintenance results in significant long-term cost savings when considering the useful life of equipment and assets with regular maintenance.

2.1. Definition and Concepts

Predictive maintenance (PdM) is an approach aimed at reducing downtime and holding costs by scheduling activities based on asset condition. An asset's condition can be determined using condition monitoring techniques, where sensors collect multiple measurements on asset operation. PdM can be classified into four categories: (1) monitoring activities which include Asset Health Monitoring; On-line Condition Monitoring; Off-line Condition Monitoring and Equipment Performance monitoring; (2) Assessment activities such as Equipment Failure Detection; Equipment Performance Assessment and Remaining Life Assessment; (3) Strategy development which focuses on Reliability Centred Maintenance analysis; Condition Based Maintenance analysis; Time Based Maintenance analysis; Wear Based Maintenance analysis; and (4) Execution activities such as Reactive Maintenance; Condition Based Maintenance; Time Based Maintenance; and Planned Maintenance [5].

PdM has become an integral part of an asset management engine in many safety-critical fields such as the oil and gas industry, medicine manufacturing, gas turbine assembly, and nuclear plants, among others. These applications are characterized by expensive and hazardous assets with lots of data recorded from condition monitoring equipment. There is generally a large ratio of condition monitoring data to failure data due to the relatively outnumbered number of failures greater than condition monitoring data. However, despite potential improvements, data-driven PdM techniques using ML algorithms have yet to be broadly adopted in practice. This paper focuses on structuring data for PdM in a way that best matches the characteristics of the data and leads to sound business decisions.

2.2. Traditional Maintenance vs Predictive Maintenance

Two strategies for getting the work are identified: Traditional Maintenance and Predictive Maintenance. These get the work done in a smart way.

In traditional maintenance, the machine is shut down when it begins to show signs of instability. Causes of instability can result from either the machine being overloaded or an unforeseen malfunction. In either case, remediation measures are taken once the machine is down, causing unavoidable loss of at least a few days to a few weeks of production [1].

In predictive maintenance, the machine is continuously monitored and critical parameters for operation are tracked. When parameters begin to reach end-of-use values for a particular process, the importance of the fact is logged, and the process is altered to take precautionary measures until the stopping point is reached. This creates a gradual decline of the machine's ability to complete the task until remediation measures are called for, allowing a wider window in which action can be taken and more options for remediation [4].

Traditional maintenance repairs machines only after they have been shown to fail, which is an undesirable situation. There is little choice on how to respond to failure and machines are usually entirely repaired that takes up too much time after failure, while also causing a loss of production during that time. Predictive maintenance also takes machine failures into consideration, but also emphasizes the continuous monitoring of equipment and tracking of critical parameters, providing insight about when the machine is approaching failure.

2.3. Benefits of Predictive Maintenance

Maintenance is an integral part of manufacturing, especially in domains where it is comparatively hard to keep the production units up and running consistently. Manufacturing in the medical field is one of those domains because failure of a production line can cause losses in production as well as put the health of a human being in jeopardy. Thus, nothing can be compromised with maintenance. As the necessity of manufacturing increases, downtimes due to maintenance have to be effectively managed and mitigated as they severely undermine the capital investment.

To understand the methods and techniques that can mitigate downtimes, it is first important to understand the fundamentals of maintenance. There can be proactive maintenance or preventive maintenance that does not wait for the equipment to seize but carries out maintenance with respect to a certain predicted model such as time-based or use-based [1]. On the contrary, the failure-driven or reactive maintenance strategy does maintenance after the equipment has already failed [4]. In the manufacturing sector, with rapidly increased competition and capital investments, there has been a clear paradigm shift from failure-driven maintenance to predictive maintenance. Here, AI techniques can play a vital role by predicting the health of the equipment and facilitating maintenance accordingly.

3. AI Techniques in Predictive Maintenance

In recent years, artificial intelligence (AI) has emerged as an effective technique for improving decision-making capabilities across various fields. Employing a wide range of techniques, AI can imitate human-level computations in tasks such as problem-solving, knowledge acquisition, planning, and reasoning. In view of the ongoing advancements in wireless sensors and the Internet of Things (IoT), considerable attention has been dedicated to the utilization of AI in manufacturing big data analysis. Various AI techniques have been employed in predictive maintenance (PM). In general, PM can be categorized into probability-based, model-based, and data-driven approaches. These approaches utilize machine learning, deep learning, and natural language processing techniques [2]. A systematic literature review of machine learning (ML) methods applied to PM can be found in [1]. Three expert orientations in PM modeling were identified: 1) exploratory foresight regarding economic and managerial considerations; 2) virtual modeling; and 3) innovative research into the methodologies for analyzing maintenance processes. A recent study on data-driven PM for pump systems and thermal power plants is focused on emerging technologies, state-of-the-art review, trends, and challenges. The scopes of interest included data-driven techniques, sensor technologies, and pump fault modes. The analysis of the conducted studies uncovered numerous challenges in research continuity and collaboration with industrial domains. However, there are opportunities for novel and significant developments in the provision and further extension of PM methods. In this context, challenges and opportunities of deep learning models for machinery fault detection and diagnosis are reviewed, comprising a description of the models' architectures, input signals, datasets, performance improvement techniques, and the achieved accuracy of fault identification.

3.1. Machine Learning Algorithms

For Predictive Maintenance, machine learning algorithms utilizing internal machine signals can be employed. It is assumed here that the internal signals of machinery are collected every sampling time tn. Frequency signals are derived from these signals by FFT, which can be used for pattern recognition. All algorithms are applied to frequency signals.

SOM (Self Organizing Map) is an unsupervised neural network algorithm, but it detects patterns (a kind of abnormal behavior) from the input patterns that are not known in advance. This algorithm has been successfully applied to failure detection for rotating machinery. Generally, it considers the distance (Euclidean Distance) between the input and the reference weights and the winner node, which best matches the input is activated. It corresponds to the inspection period (tn) of the input pattern. The weight vector of the winner node is updated using the learning rate and neighborhood function.

The KNN (K-Nearest Neighbors) algorithm is not a learning algorithm. This algorithm finds K reference weights in the reference weights database in the distance order. If this K number is larger than 1, the voting is performed among K reference weights, and the one that has the maximum agreement is selected. If this K number is equal to 1, only one reference weight is selected, which corresponds to the particular instance of this case. The class of the selected reference weight is ascribed to the current input pattern. This algorithm has been successfully applied to the diagnosis for rotating machinery.

The SVM (Support Vector Machine) is a learning algorithm that creates the decision boundary with the support vectors of the class. This 'maximum margin hyperplane' is established in a higher dimension, in which the different classes are well separated. Consequently, this boundary becomes a decision rule. New input patterns are classified into one of two classes by indicating which side of the boundary they fall on. This disturbed SVM is utilized for the abnormal behavior detection in the manufacturing process.

3.2. Deep Learning

Deep learning is an advanced machine learning technique that employs neural networks with multiple hidden layers within its architecture. By continuously adjusting and learning from the weight coefficients in the hidden layers, deep learning aims to optimize these networks for the particular problem being addressed. This system's ability to manage and analyze large amounts of data makes it particularly effective. Deep learning techniques are often applied to datasets that are either exceedingly large or too complex for conventional predictive maintenance (PM) approaches. By employing these systems, high-level features can be automatically captured from raw data, thus avoiding the need for manual feature extraction and allowing successful analysis of images, audio, and raw sensor data. For these reasons, deep learning PM techniques have recently gained popularity in a wide range of industries [6].

Deep learning models have been utilized in numerous large industries, including airports and railways, and are presently being tested in various other sectors, such as power generation, automotive manufacturers, oil and gas, and life science and healthcare industries. Convolutional neural network (CNN) models have been successfully implemented on fan data collected from a turbofan engine, with the CNN5 model achieving the best health state classification results. Images due to the occurrence of several faults were obtained, and a CNN was used to classify these faults into eight different categories. These models' accuracies ranged from 92.95% for the AlexNet CNN topology to 96.72% for the CNN5 topology [2].

3.3. Natural Language Processing

Recent advancements in Natural Language Processing (NLP) have opened exciting new avenues for text-based approaches to predictive maintenance (PM) [2]. Modern NLP techniques can analyze the exponentially growing textual data available in organizations to augment existing predictive capabilities. In addition, manufacturing capabilities are changing from utmost mass production to customized mass production, where small batch production will be the standard. Due to this transition, maintaining the competitiveness of manufacturing companies has become highly challenging. Thus, the combination of large amounts of production data and modern AI techniques offers manufacturing companies incredible opportunities to make smarter business decisions. Therefore, this trend is growing interest in text-based PM.

Text-based PM approaches use large amounts of textual data, such as operating manuals, inspection reports, repair histories, and knowledge bases, to predict failures or maintenance needs [1]. However, text-based PM is an unexplored area compared to statistical and model-based PM approaches. Currently, state-of-the-art PM research focuses on exploring time-series data. This, however, severely limits the effectiveness of PM's predictive capabilities, as an empty predictive maintenance account story is only told by time-series data.

4. Implementation of Predictive Maintenance in Medicine Manufacturing

A comprehensive predictive maintenance system aims to decrease maintenance costs and improve the reliability of the machines used to manufacture medicines. Implementing predictive maintenance in medicine manufacturing includes processes like data collection, development of models, training of models, and integrating them with the existing systems. The role of sensors is to collect engine health parameters such as temperature, pressure, rotational speed, and others. These parameters are collected along with time and date to promote future monitoring. Monitoring medicine manufacturing requires careful selection of sensors to avoid contamination [4]. After collecting the data, it needs to go through preprocessing steps. The data are filtered to remove the outliers due to system failures. In this step, some data points are removed as they are more than 3 standard deviations away from the average. It is crucial to note that the data is filtered only on the compounds selected for modeling. Other compounds are considered "uncontaminated" and kept as they are. The filtered dataset is normalized so that data for different sensors can be used together [7]. Both the original and compound-fluctuated dataset were scaled between a defined range for all parameters using min-max normalization. A unique trade-off in application forms exists for different batches. If paralleling the alarm threshold with either batch, a higher occurrence of unwanted alarms would happen for the other batch. In manufacturing, downtime reflects on output quantity. Plants work in shifts, which compresses batch times even further. In a stress scenario, even correcting an engine fault, production can be lost as medicines must be analyzed before release.

4.1. Data Collection and Preprocessing

Simultaneously with the selection and configuration of relevant software tools, modeling and preparation processes take place. Modeling and preparation processes are grouped under two common headings: data collection and data preprocessing. These two topics cover the essential first steps of implementation [8].

Data collection refers to the gathering of all sorts of relevant data, which is the basis for the predictive maintenance model. In the case of predictive maintenance for ASTM Blending and some remaining parallel batch processes, different types of documents are collected. These documents span the complete lifecycle of the assets and contain information on the operation of the assets, equipment incidents and maintenance actions, parameters describing the architecture and the role of the machine in a system, and key performance indicators that measure the performance of the machine. Operational data from the process signals monitored by the historian is collected in addition.

The next task is to pre-process the collected data to ensure its usability in predictive maintenance models. A considerable amount of effort is spent here. Potentially useful data fields are identified, and other nuisance values that are not useful for predictive maintenance are filtered out. Most of the time, data arrives in raw formats that need to be transformed into a structured database format. Moreover, the data is processed to improve the quality of the data. Missing values, erroneous values, and outliers, which can distort the modeling results if left untreated, are corrected or filtered out [1].

4.2. Model Development and Training

[9]

As preliminary model development, a data-driven AR(2) process is simulated as input (x0) with a 10% chance of outlier presence in timestep 190 and a change in process mean. Initially, x0 is stationary with a Gaussian fluctuation of 100±5 as shown on the top due to Gaussian noise up to 0.01. The lower plot shows the second input stream (a metric in machine usage) with added outliers after timestep 195 with values greater than 115. Exogenous variables (dummy variable) can be included as input through design to indicate these other changes. This hint allows diverse learning on the input stream and/or captures mistakes, like flat line output, as a clear observable input change.

4.3. Integration with Existing Systems

Regarding the integration phase, predictive maintenance is anticipated to be seamlessly integrated into the existing equipment infrastructure. The predictive maintenance systems examined in this dashboard have already been validated on multiple datasets within manufacturing companies, with predictive maintenance and other AI initiatives anticipated to be introduced within these companies in the near future. However, the potential challenges in integration with existing IT infrastructure are considered. On the one hand, the Cloud-based AI infrastructures, implemented by companies in the relevant manufacturing industry segments, keep most of the data on-premise to meet regulatory requirements. On the other hand, smaller manufacturing companies often use older equipment and have limited technological awareness. Consequently, the designers of the predictive maintenance systems aim for an "easy-to-use" technology, which standardizes data preprocessing and model development using the same process within each segment [10].

Importantly, in order for the predictive maintenance solutions to be successfully adapted to the individual needs of different companies, they must be flexible and modular by design. As a result, with early AI design involvement from the manufacturing companies, the predictive maintenance systems could be structured in a modular way such that different designs could be assembled to meet the technological capabilities of each company's production line as well as the nature of their data. This would allow individual challenges to be tackled, such as, linking IT infrastructures, flooding off the data, and extracting important features from the production environment [11].

5. Case Studies in American Medicine Manufacturing

Company A has implemented predictive maintenance and data analytics across its US manufacturing sites to enhance equipment reliability, reduce downtime, and drive operational excellence [7]. Real-time data from processing, filling, packaging, and sterilizing equipment were collected and sent to cloud servers. This data was then analyzed using sophisticated algorithms to provide actionable task recommendations. What began as an experiment at one site has expanded to all 12 domestic manufacturing sites, utilizing various technologies and data analytics from local process experts. The site team developed a maintenance compliance tracking dashboard that highlights task completion compliance per equipment per month. Qualified engineers receive weekly summaries of upcoming tasks and overdue equipment to take corrective action. After implementation, compliance improved from 50% to more than 90% within two months, and the improvement continued. PM tasks that impact production significantly are reviewed by process engineers every month. Cost analysis and recommendations for improvement are completed for the top 20 equipment. This plan examines factors like failure type, hourly production cost, compliance data, and process conditions during checkups. Several recommendations have been noted based on this analysis, including the need for task interval adjustment, PM capability assessment, modification of existing tasks, and training for local technicians.

Company B has reported mixed experiences regarding predicting equipment failures. PM on several equipment was enabled in different factories using a fleet-wide data platform for remote access to server data. Current PM events are monitored and completed in time on six equipment, with a consistent decline in events pending over 91 days. Fleet-wide PM backlogs have also reduced by more than 100, with nine minimum PM frequency equipment. HMB and TCM weekly reports and plans have been implemented. The operation of one vessel was halted, and recordings of additional fouling/cleaning were shared with French domain experts for improvement. Six vessels had HP exceeded in about 30% of periodically recorded results, and root causes were investigated and resolved. However, PM tasks on five vessels involving temperature and design calculations are required but have not been completed since 2021. These PM tasks were too complicated without a modeling program, and it was suggested to create a centralized technical group or contacts with equipment vendors for mathematical modeling. The MPF task for PM on design changes based on observed operation conditions was also not satisfied. It is suggested that if design calculations have never been carried out, this is an efficient avenue for PM enhancement [1].

5.1. Company A: Implementation and Results

The focus here is on the experiences of Company A, an American medicine manufacturer, in adopting predictive maintenance solutions to alleviate extended downtimes of key production machines. Company A specializes in producing and packaging various forms of prescription medicines for its partners, including universities, other pharmaceuticals, and hospitals. A significant performance target for Company A is to have a minimum machine uptime of 95%. Company A is one of the largest producers of the U.S. medication market, packaging 7.5 million units each week with an annual packaging capacity of 500 million units.

However, unscheduled production downtimes that are caused by machine defects for various machines inside the facility, including tableting machines, capsule printing machines, blistering machines, bottling machines, etc., often exceeded this performance target, leading to unwanted customer complaints and penalties.

To address this issue, among various kinds of intelligent systems, artificial intelligence-driven predictive maintenance system solutions were adopted to predict the machine failure of a packaging machine prior to the failure under normal operation conditions, even at different consumption rates. Packaging machines like the blister machines used in Company A undertake multiple processes, including automatic feeding, blister feeding, etc., prior to the final inspection and packing. As the scheduling was complex due to many loads in each process and intelligence built in different machine suppliers, the implementation was only deployed on the last insulating machine, AW4, with an operating rate of about 35% for all packaging machines inside Company A [12].

As a result of this system implementation, the packing performance of the AW4 machine was improved by 37.5% after a comprehensive comparison before and after the implementation. Both the types of downtimes and the downtime analysis indicated that the system deployment identified various types of downtimes and mitigated many of them with countermeasures proposed by machine suppliers. The positive outcomes of this machine learning-driven predictive maintenance system have been further verified outside the frame of modeling accuracy, machine statistics, and downtime accuracy analysis.

5.2. Company B: Challenges and Solutions

Company B's case study highlights some of the challenges encountered belonging to three broader categories: modeling, data acquisition, and technology adoption. Adherence to FDA regulations has slowed system development because the choice of technologies smoothed the path toward regulatory issues. To address the challenges in building and refining additive machine learning and physics-based predictive maintenance models, this case study presented an innovative solution in the form of a cloud-based platform (IoT software + Models) that allows localized in-house machine learning/modeling capabilities while adhering to the FDA cloud computing policy. This cloud-based platform operates through a Software as a Service (SaaS) business model, allowing rapid development and improvement of models as issues arise or new needs are identified. For sensors used in vibration-based data acquisition, developing an in-house low-cost solution allowed for rapid adaptation while solving regulatory issues in choosing commercial sensors [13]. The interaction and progress of the data acquisition and modeling teams can be a double-edged sword; more interaction often leads to successes, but the absence of recognition can have detrimental effects. Team members must set reminders and meet regularly to be mindful of both aspects. Lastly, the special task team approach to monitoring model performance was crucial because, without a predefined structure and timeline, the problem could be neglected. This highlights the importance of motivation and effective hardware tracking at the operator level. Health and capacity monitoring of the most critical assets are therefore essential but insufficient; sufficient hardware tracking plans and operator incentives are also important. On the technology adoption side, this study highlights that purely software-based/artificial intelligence innovations require significant time and resources to be fully embraced and used to their potential. Unquestionably integrated hardware solutions are far easier to adopt as operators are more likely to recognize and trust the technology [1].

6. Benefits of AI-Driven Predictive Maintenance in Medicine Manufacturing

AI-driven predictive maintenance can greatly enhance medicine manufacturing in American industries, reducing downtime, improving production losses. Preventative maintenance estimates the remaining useful life of a machine using statistics, helping to fix it before it breaks down. Big data and IoT allow monitoring manufacturing equipment, detecting abnormal vibrations/electrical consumption, and avoiding downtime based on prior failures. AI-driven predictive maintenance [1] achieves this disadvantage by fully adopting statistical modeling, allowing chemistry/automated medicine manufacturing processes with no prior statistical knowledge to benefit. It also saves on research and development costs and shortens production line time.

Downtime is a major loss in any manufacturing process, more if chemical, like medicine manufacturing [2]. AI-driven predictive maintenance reduces production losses, lower labor/energy costs due to uninterrupted operations. AI-driven predictive maintenance addresses these major disadvantages.

6.1. Reduced Downtime and Production Losses

The application of AI-driven predictive maintenance in the medicine manufacturing industry leads to remarkable reductions in downtime and production losses. In the production line, every second of downtime costs money [14]. The SMART solution developed rapidly detects shifted devices and issues a warning signal to engineers in seconds, facilitating fast troubleshooting and reducing downtime to minutes instead of hours or days. As the number of machines in a production line scales up, AI-driven SMART simplifies the monitoring and controlling task for engineers. Engineers can devote their time to more critical tasks instead of repetitive monitoring. Moreover, with full-machine operation health records, the solution identifies devices that frequently shift and assists factories in improving machine stability. With SMART, factories save USD 700,000 annually in downtime and 150,000 USD in production loss.

In addition to the production line, the manufacturing process also involves the research and development of new medicines that require complicated tests in the laboratory. New after lab devices such as HPLC or UPLC are introduced to increase efficiency, but technicians must monitor the devices for potentially failed tasks. With AI-driven SMART, factories save USD 200,000 annually in production loss incurred by unexpected failed tasks. In E-078, 5-non-breathable anti-viral wipes were produced. E-078 has been successfully approved on 5-2022 and has been produced in a pilot scale. However, the built-up of positive controls in the Bioieatreatment System (BBS) and Biological Safety Testing (BST) post-processes led to the batch failure for the first 4 batches of wipes. With data analytics by AI-driven SMART, properly bio-degraded positive controls have been discovered. The successful approval of biodegradable positive controls and the recommendation of BST microbiological testing at day 8 resulted in the business of USD 5 million annually [1].

6.2. Cost Savings and Efficiency Improvements

The financial impact of AI-driven predictive maintenance on manufacturing is apparent in the cost savings and efficiency improvements it provides. AI-based predictive maintenance has been widely adopted in sectors such as manufacturing, healthcare, gas and oil, electric grids, and aviation for its tangible benefits [5]. Companies surveyed in these industries have saved tens of millions of dollars by integrating AI-driven predictive maintenance. The following section presents a detailed analysis of the financial impact of AI-driven predictive maintenance to provide a better understanding of its real value.

Manufacturers implementing AI-driven predictive maintenance have generally realized substantial cost improvements. The deployment of an AI-based predictive maintenance solution saves manufacturers 30 to 40 percent on maintenance, resulting in an investment repayment period of less than one year. Overall, the average yearly savings from investments in AI-powered predictive maintenance should be around $300,000 per machine. The average ROI on AI-driven predictive maintenance across all discussed use cases is approximately 20 percent in the first year after investment, and 25 percent in the second year [15].

7. Challenges and Future Directions

The role of AI-driven predictive maintenance in the American medicine manufacturing ecosystem is crucial. However, certain challenges need to be addressed to promote its growth and prevalent adoption in the existing digital and 4IR frame. Some barriers to the growth in AI usage also need addressing, particularly the training of technicians and plant operators in interpreting the outcomes and evaluations from AI tools and technologies [16]. The problem landscape also includes the growing misalignment of data infrastructures, introduced by data practices and incompatibilities [1]. In turn, tech giants play a significant role in and through social media platforms to rescale community-based struggles to broader audiences and make activism digitally visible. In the context of AI tools, there are also risks of opaque algorithmic predictions, automation of blame, and potential biases reflecting existing decolonial inequalities.

A dual strategy of analysis and experimentation is essential for detailed examination in specific infrastructures and subsequent exploration of upsides through alternative approaches and experiments. Through an assemblage framework, platforms can be seen as an articulation of social, technical, financial, political, legal, and cultural relations mediated by social media. Looking at empirical studies of specific platforms, imaginaries of the decolonization of the internet have been articulated through resistance movements, manifestos, codes of conduct, and fields of experimentation, including platform cooperatives, participatory budget efforts, citizen-journalism portals, tech justice networks, and tech-for-good initiatives. Currently, existing AI and analytics technologies are considered black boxes, unable to interpret themselves.

7.1. Data Quality and Availability

Data is the first of the nine success factors for predictive maintenance implementation and is also positioned first for a reason. Experts within the predictive maintenance field lowered the possibility of fruitful predictive maintenance development due to low data quality standards [17]. The desire to enter predictive maintenance analytics should be accompanied by high-quality data. A major challenge for maintenance and reliability in the manufacturing sector is data availability. Manufacturing companies face a much more complex challenge in terms of data availability compared to other domains [18]. To enter a state-of-the-art predictive maintenance analytics and improve day-to-day maintenance actions on the shop floor, manufacturing companies must prioritize the data collection process and standardize data quality and requirements.

It was learned that in the situation where respective data quality standards are not fulfilled, it is preferable to filter which machine within the production fixture should hold a predictive maintenance solution (or Brick Solution 2 in the case company) and which should be transferred to a more basic solution (or Brick Solution 1 in the case company). There are machines at the case company that clearly do not fulfill the necessary requirements when moving forward with predictive maintenance. Additionally, predictive maintenance cannot be used with a machine where there is no basic condition monitoring equipment installed. Companies that attempt to enter predictive maintenance analytics without any basic condition monitoring equipment installed will most likely face a situation of low data quality standards with no possibility to turn it into higher data quality standards.

7.2. Interpretability and Explainability of AI Models

Interpretability and explainability of AI models are central issues to be addressed when applying those technologies in real-life applications, especially in context-sensitive, safety-critical, or regulations-constrained contexts such as medicine manufacturing. The general challenge associated with this issue is to understand and justify the decisions made or influenced by AI. In the case of AI-driven predictive maintenance, guaranteeing the robustness of failure predictions or recommended maintenance actions is crucial to avoid unsafe decisions or, conversely, call for unnecessary maintenance actions [19].

The challenge is especially difficult with AI systems based on deep or complex models, whose translational-invariance designs and large number of parameters lead to data-driven emergent behavior extremely hard or even impossible to understand, even for the engineers who designed and trained the models [20]. In the context of prescriptive maintenance, explainability is a multi-faceted issue. Maintenance actions can be decided not only based on predicted failure events but also taking into account business constraints such as available spare parts, scheduled maintenance operations, etc. In all those aspects, understanding the relative importance of the input variables used by the models or their derivative algorithms is paramount. Such understanding is also crucial in other domains such as fairness, equity, or liability favoring the emergence of trust in maintenance actions based on those AI models. Several methods exist to analyze the decisions made or influenced by AI models.

7.3. Ethical Considerations

AI-driven predictive maintenance systems are being developed in various fields to anticipate problems before they occur, which can help avoid unplanned downtimes. In medicine manufacturing, the sector responsible for producing life saving drugs and equipment, the use of AI-driven predictive maintenance is still in its infancy. Worrying for the tens of millions of patients and potential patients that depend on the regular availability of medicine every day, consequences of unplanned downtimes can be dire. Besides serious health issues resulting from patients not receiving required medication on time, heavy fines can be imposed on both the medicine producer (for not delivering the products) and the state (for not providing guaranteed health care). Additionally, downtime lengths can greatly vary. Generally speaking, the longer a downtime continues, the higher the consequences and damages are. Given how well a predictive maintenance system could contribute to the overall uptime, it is crucial to investigate how this system could be built and implemented [21]. Since AI is involved, ethical considerations pertinent to its application are examined.

Close selection of what machine learning models to use is one of the first steps to take. These models must be able to deliver accurate predictions without providing wrong alerts about the operating state of the examined machine or sensor, which is similarly true for non-AI-driven predictive system solutions as well. It is worth noting this distinction up front however, as with non-AI-based solutions an alert can simply mean that a specific threshold condition is met, while with AI predictions often constitute continuous values. These values must then be interpreted by a well-formed triggering function, in which case also the threshold condition is included. Furthermore, it is important to define what type of unplanned downtimes should be considered. For example, an avoided problem could be the assessing of equipment condition relative to operating norms and use of that knowledge to alter or reject its operating conditions afterwards. However, in this case the downtime would continue, although in a different form than the originally anticipated one and still undermine the production efficiency measures taken [22]. Care must also be taken with ethical considerations and possible biases while one of the selected models is a neural network.

8. Conclusion and Recommendations

The analysis of the role of AI-driven predictive maintenance (PdM) technology in reducing downtime in American medicine manufacturing demonstrates the potential that this technology has for improving productivity and efficiency in these sectors. A critical examination of concerns regarding false positives, data privacy, and accessibility also emphasizes the fact that AI-PdM can help companies transition to a new way of approaching downtime, especially in the wake of the pandemic. Technologies for AI-PdM are becoming increasingly affordable, and there are many providers with off-the-shelf solutions, especially in industries such as manufacturing.

The following recommendations are made regarding the adoption of AI-driven predictive maintenance technology: 1. Continued public and private investment in nationwide and industry-wide connectivity conditions—data interoperability at all levels (company, industry, state, federal, global) will be crucial for AI-PdM technology to flourish. The recent introduction of the US Inflation Reduction Act may help to open up funding opportunities for many sectors that have not fully integrated the digital revolution into their operational frameworks, 2. Further public and private investment into establishing minimum training, certification, and onboarding standards for IT staff across industries. The lack of IT staff in medicine and healthcare has been documented and will remain attractive for hackers and ransomers as a low-hanging target, 3. Formation of industry commissions/governmental agencies to regulate the quality and integrity of attorneys specializing in liability policies regarding uptime, downtime, and operational losses [1].

8.1. Summary of Findings

In American medicine manufacturing, downtime refers to the time when a production machine, manufacturing line, or facility is shut down temporarily or indefinitely while awaiting a repair or adjustment. Downtime is undesirable because it causes a significant loss of revenue as well as other disruptive effects [23]. Although unplanned downtime can never be entirely eliminated, it needs to be minimized. AI (artificial intelligence)-driven predictive maintenance is a novel maintenance approach that can significantly mitigate the negative effects of unplanned downtime. AI technology is equipped in a growing number of manufacturing machines and facilities. With AI technology, enabling data-driven analytics, such as predictive analytics, predictive maintenance, and scheduling optimization, is possible [1]. Such smart factories are capable of executing autonomous manufacturing operations. Such automation can eliminate the need for specific skillsets of workers which have become increasingly hard to find, especially in the face of the demographic changes of an aging population and workforce. Therefore, the immediate future of factories is expected to be entirely AI-driven and autonomous.

8.2. Recommendations for Industry Adoption

Although the technological evolution of AI-driven predictive maintenance systems has been investigated, questions remain regarding cost-benefit analysis, return on investment, and the adjustment of business plans. These aspects are crucial to ensuring a convincing business case for the implementation of this technology. Although the immediate implementation of AI-driven predictive maintenance solutions in larger batches across large physical systems globally may not be feasible, preliminary steps can support and facilitate this evolution. In such a case, precautionary measures should be taken to secure political measures, addressing the common situation of a global race to the bottom, where the first player advancing the technological solution has a competitive advantage over others [1].

To prevent the expansion of ongoing structural and safety problems, it may be worth considering the implementation of early warning signals. AI-driven technological solutions can be recommended to smaller companies/bricks who cannot afford an implementation on their own. The implementation can also be considered for similar industries, which would be understood as a collaborative effort. Additionally, in any such effort, sufficient obligatory standards should be outlined, supported by a strict legal framework [18]. The implementation of preliminary risk assessments, periodic evaluations and requirement updates may need to be combined with strict monitoring, privileges termination, and legal consequences. Politicians should advocate these precautionary measures while industries may consider investing in more basic technologies or reinforcing existing predictive maintenance/monitoring solutions.

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