The Role of AI-Driven Predictive Maintenance in Enhancing U.S. Pharmaceutical Manufacturing Operations

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1. Introduction

Pharmaceutical manufacturing is essential for the production and sale of pharmaceutical and biomedical products required for curing diseases. In recent years, pharmaceutical manufacturing improvements have gained increasing focus due to the COVID pandemic, compelling the industry to become more agile and flexible to ensure the drug supply chain's efficiency and robustness. Advanced systems, valves, sensors, or other equipment are required in building facilities. These items are considered critical assets as they are directly involved in the manufacturing of sterile drug products, thus affecting drug quality, safety, and efficacy [1]. Additionally, if equipment is not available during the process flow, productivity and material throughput would be lost. Such interruptions heavily impact production, as data suggests a strong dependency on equipment scaling on the manufacturing process duration. Therefore, equipment condition monitoring approaches are required to ensure the health of manufacturing-critical assets and to initiate action if necessary. Suitable maintenance actions could be the difference between smooth production and severe product supply problems, with substantial financial repercussions for the companies involved. For instance, a product shortage could exceed the estimated annual revenue of $1.8B for a typical vaccine production facility. In addition, costly penalty fees for contract defaults could arise. A terrestrial approach based on whether assets are degrading or no longer suitable for use should be considered when developing maintenance concepts.

An AI-driven approach is proposed to leverage data directly generated by observed equipment along the process. By implementing this concept, a data-driven condition monitoring system could be established to consider equipment faults on a longer time scale, relative to the current state-of-the-art, which only detects process-critical events such as temperature or pressure deviations [2]. Consequently, options to act upon this information with maintenance actions would prevent unintended knowledge loss and avoid production interruptions through equipment faults. Moreover, process monitoring data can be used for equipment condition monitoring if sufficiently assessed. Methods of modeling and classifying equipment faults remain a subject of research. This work is focused on building a generic data-driven monitoring system of equipment condition in sterile drug product manufacturing based on 30-month data from an integrated biopharmaceutical manufacturing facility equipped with different asset types such as batch reactors, plate heat exchangers, membrane filters, valving clusters, etc.

1.1. Background and Significance

Throughout the years, predictive maintenance methodologies have evolved gradually from time-based techniques to condition monitoring methodologies, followed by various advanced approaches. Recently, Artificial Intelligence (AI) has gained attention among decision-makers in manufacturing settings. AI-based techniques can efficiently manage and analyze vast amounts of process data and offer unprecedented opportunities for predictive maintenance applications. Even though the definition of AI is broad and embraces a wide range of applications, it generally refers to the use of data, algorithms, and automation to emulate human cognitive capacities [1]. However, AI applications also include rudimentary statistical tools, which have existed and been used in industrial settings for several decades, and advanced methods such as deep neural networks.

Predictive maintenance (PdM) is intended to predict upcoming equipment failures based on the analysis of equipment condition and process data. Thus, it can potentially avoid unexpected production interruptions and costly product losses. The pharmaceutical industry is an economically large sector and highly regulated. In addition, it is an industry with high product values, where unexpected production failures lead to expensive product losses. Therefore, a strong incentive exists to explore the potential of AI applications in pharmaceutical production to avoid production stops. Furthermore, the operations in pharmaceutical manufacturing plants are mostly continuous or semi-continuous and closely connected to process analytical technology (PAT). Thus, the design of equipment and processes will enable the industrial implementation of advanced PdM strategies, which can be investigated based on long-term historical data.

2. Foundations of Predictive Maintenance

Preventive Maintenance originated as a replacement practice in "Breakdown Maintenance" that aims to avoid forcing the facility to operate in an error and unintended condition for long periods. Such a work style usually grounds to a great waste of unforeseen costs to the industry, such as missing due delivery dates or repairs [3]. In those early days, the industry moved toward the "plan" of time interval practices of mechanical nature as preventive maintenance. This action but couldn't avoid an economic disaster since it had to stop Running Already Well Assets (RAWAs) after a determined time of operation, independently of their actual conditions. Similar to applying the same medicinal treatment, the same dosage and medication may cure some patients but aggravate conditions in others.

A major improvement was the "strategical" preventive maintenance practice of condition monitoring based on checking the conditions of the assets being considered. Such practices would monitor variables that characterize the healthy condition of the assets with the intention of understanding the needs for action before such conditions being outside normal levels. This strategic change in focus, in addition to the technological improvement of computer and instrumentation capabilities, increased the level of complexity in the mathematical models that stemmed in the last two decades. Such models consider deterministic, probabilistic, or multi-stochastic suppositions derived from the statistics underlying the failure distributions being considered for analysis [4].

2.1. Concepts and Principles

This section further elaborates on the concepts and principles that form the foundations of predictive maintenance. Three aspects of this research topic are described: the general definition of maintenance in industrial processes, elaborating on the differences between reactive, preventive, and predictive maintenance and the motivations for moving away from corrective maintenance; the general definition of predictive maintenance and how machine learning can help carry this out; and a more detailed overview of the various statistical analyses that can be carried out with predictive maintenance.

Maintenance can be defined as a set of activities directed towards preventing and dealing with unwanted situations that could impair the normal operation of an industrial process. Such activities can either consist of repairs, refinishing, checking or replacement of equipment or components. Equipment maintenance is essential for preventing unplanned stoppages of production lines. Indeed, malfunction can lead to dire consequences like loss of production, damage to equipment, or accidents. Thus, cutting-off unplanned stoppages is of the utmost importance to the profitability and safety of the manufacturing process. There exists the possibility to either act before or after a malfunction has occurred. On one side, there is corrective maintenance, which implies taking action after the failure has occurred [5]. On the other side, there spans a set of maintenance activities that aim to avoid the failure beforehand: these are preventive maintenance actions. These actions consist of scheduled activities, carried out either at fixed times (time-based preventive maintenance) or based on the condition of the equipment (condition-based preventive maintenance). Nevertheless, such actions do not guarantee that the failure will not occur, as unforeseen malfunctions may still arise between maintenance intervals.

Machine Learning (ML) technology helps identify the fault lines by predicting the failures at the right time and thus utilizing resources effectively [4]. The operator at a particular manufacturing plant can get the updates of the manufacturing unit. The data fetched from the sensors is cleaned and pre-processed to extract important features for data analysis and finding patterns and correlations among the parameters. The cleaned data is then used to train a machine learning model, which would predict the parameter values over a period of time. Different models were trained on the parameters and their accuracy was calculated. Long short-term memory is an artificial recurrent neural network (RNN) architecture used in the field of Natural Language Processing and Deep Learning. LSTMs have been established to address the vanishing gradient problem that can be encountered when training traditional RNNs.

3. AI Technologies in Predictive Maintenance

AI technologies are being widely adopted in various healthcare applications. One application involves the use of AI to divide cells into distinct phases of the cell cycle from a time-lapse microscopy movie. It automates the analysis and aids biologists by facilitating investigations of many different cellular processes, which is challenging in cell-based therapies. Furthermore, AI technologies can be employed to analyze images of fundus cameras to evaluate the progression of the disease non-invasively over time. The AI algorithms assist ophthalmologists in the management of retinal diseases, where timely intervention is critical. AI is also being harnessed in the pharmaceutical sector for enhancing supply chain management and supporting decision-making processes in R&D and market strategies, which improves the outcome of the healthcare sector.

In India, AI is optimally being used to predict the demand of drugs and accordingly manage the inventory based on NLP technologies, which ensures that medications reach the people who need them the most. Under the BIRAC/DBT program, the University of Hyderabad is developing such an AI-based tool, which can help in averting medication wastages due to oversupply and unavailability of certain drugs due to increased demand, thereby resulting in economic losses. Furthermore, Blockchain technology is being explored in India in the pharmaceutical sector to decentralize the supply chains and enhance the trust and data-sharing capabilities across the supply chain in order to cut down the costs.

AI can play a significant role in laboratory management. Pharmaceutical companies invest millions of capital in research laboratories every year; hence, their optimal performance is essential to handle the cost and time pressure. With the increasing complexity of experiments and consequently the rising amount of data, it is becoming a challenge for researchers to optimally utilize laboratory resources to achieve the best experimental results. To handle this issue, AI is being employed to automate the workflow and optimize laboratory parameters for robust results [3]. By improving the performance and reliability of the pharmaceutical manufacturing processes, AI technologies can enhance the safety and efficacy of pharmaceuticals.

3.1. Machine Learning Algorithms

Specific attention is given to the machine learning algorithms utilized in AI-driven predictive maintenance. These algorithms include a combination of supervised and unsupervised learning methods. Within the supervised learning category, Random Forest, Decision Trees, k-nearest neighbor (k-NN), Support Vector Machines (SVM), and Logistic Regression are employed for classification. For regression tasks, Random Forest, Decision Trees, k-NN, Support Vector Regression (SVR), and Logistic Regression are utilized. On the other hand, the unsupervised learning category encompasses K-means and Hierarchical Clustering algorithms.

Random Forest is an ensemble learning approach designed for classification and regression tasks, harnessing the power of multiple Decision Trees [5]. Decision Trees are flowchart-like structures that utilize branching methods to illustrate statistical hypotheses and decisions. In contrast, k-NN is a non-parametric lazy learning algorithm based on the "guilt-by-association" principle, classifying new observations based on their similarity to known observations. It offers advantages in simplicity, training time, and accuracy, requiring no distributional assumptions. SVM is a supervised algorithm that creates linear separating hyperplanes in a high-dimensional space to classify observations [6]. With a regularization parameter controlling the margin width and a penalty parameter for misclassification adjustments, SVM guarantees finding a global optimum hyperplane solution.

4. Challenges and Opportunities in Implementing AI-Driven Predictive Maintenance in Pharmaceutical Manufacturing

The pharmaceutical industry is heavily regulated to ensure that patients receive safe and effective medications. Drug manufacturers must comply with Good Manufacturing Practices (GMPs), which emphasize the need for effective equipment maintenance programs and minimization of unplanned equipment downtime. Experts recommend using proactive maintenance methods, including predictive maintenance (PdM). However, implementing PdM in GMP-compliant environments poses unique challenges. Before considering PdM applications, it is essential to assess the manufacturing environment and compliance demands of the production area in question [1].

Pharmaceutical manufacturers are currently confronted with more stringent regulatory, economic, and environmental pressures. Initiatives such as continuous manufacturing and new manufacturing processes (e.g., more potent drug substances) are ongoing but can only be implemented if commercial manufacturing equipment is already available and qualified. As a result, manufacturers are exploring opportunities for more efficient use of existing equipment, one of which is intelligence-driven maintenance strategies. In GMP-compliant environments, this must be done while fulfilling additional requirements to ensure the safety and efficacy of the drug products manufactured due to the maintenance strategies' effect on the equipment's intended use. Thus, it is best to consider the prospects of PdM applications in a stepwise and methodical approach starting from a thorough understanding of the compliance demands that the equipment is subject to. For potential opportunities from a manufacturer perspective have a look at chapter 7.

4.1. Regulatory Compliance

Regulatory compliance is one of the most critical considerations regarding the implementation of AI-driven predictive maintenance in U.S. pharmaceutical manufacturing operations. This is true for any manufacturing-related technology imposed by regulations of the U.S. Food and Drug Administration (FDA) or the EU's European Medicines Agency (EMA). With COVID-19 vaccines approved by the FDA, at least 24 FDA-licensed pharmaceutical manufacturers in the U.S. are tasked with maintaining, in a state of control, and documenting the manufacturing, testing, verification, and upkeep of drug products and equipment in compliance with regulations [1]. Given this need to comply with regulations, the implementation of AI-driven predictive maintenance raises concerns regarding control and accountability. Questions arise about the responsibility of faulty prediction development and ultimately wrong equipment upkeep that may cause unplanned costs, product loss, and safety violations.

Of the eleven risks or challenges outlined in this analysis, four key challenges are particularly salient considerations proactively acknowledging and addressing them during implementation. First, models predicting future equipment conditions have to be auditable individually. Current AI-driven condition and reliability prediction models are often opaque knowledge systems for their users [2]. This lack of transparency raises concerns over accountability. In case of falsely optimized maintenance actions related to downtime, unplanned costs, product loss, and safety violations, it is unclear who is responsible, AI-model developers, manufacturing process engineers, or maintenance managers? Public scrutiny about the decision-making accountability gap of intelligent technologies has risen, and this trend will continue in the pharmaceutical industry. External audits and internal control teams will evaluate whether digital services and technologies, including AI-driven predictive maintenance, are working reliably considering compliance with manufacturing and product quality mandates.

5. Case Studies and Best Practices

[1]

Best Practices for AI-Driven Predictive Maintenance Implementation Based on these case studies, several best practices can be identified for successful implementation of AI-driven predictive maintenance in pharmaceutical manufacturing:

1. Data Quality and Integration: Ensure high-quality data collection and integration from various sources, including sensors, historical records, and process monitoring data. Invest in data cleaning, normalization, and preprocessing to improve the quality of input data for AI models [2]. 2. Investment in Advanced Technologies: Invest in advanced technologies such as IoT sensors, edge computing devices, and cloud platforms to enable real-time data collection and processing. These technologies can facilitate the deployment of AI models and monitor equipment conditions continuously. 3. Cross-Functional Collaboration: Foster collaboration between IT, operations, and maintenance teams to leverage their expertise in data analytics, process understanding, and equipment maintenance. Cross-functional teams can develop more accurate and relevant predictive models. 4. Phased Implementation Approach: Adopt a phased implementation approach starting with a pilot project on critical equipment. A phased approach allows for the gradual scaling up of AI models, reduced implementation risks, and opportunities for continuous learning and improvement. 5. Continuous Model Monitoring and Updating: Continuously monitor the performance of AI models and update them regularly to reflect changes in equipment design, operating conditions, or process parameters. Regular model updates ensure the accuracy and relevance of predictions over time.

5.1. Successful Implementations in the Pharmaceutical Industry

Predictive Maintenance has been widely discussed, yet practically untested in the context of other Industry 4.0 functionalities. The research aims to fill the gap and presents a multi-area approach to enable predictive maintenance in flexible manufacturing. In constructing predictive maintenance scenarios, the focus is to enhance the operations of small and medium enterprises (SMEs) through the adoption of Industry 4.0 technologies. A mathematical model is developed to support decision-making with regards to predictive maintenance schedule for multiple machines and components. The model takes into consideration machine data such as operation, condition, and maintenance data. By developing scenarios and the mathematical model, tips could be obtained to boost the chance of successful implementation of predictive maintenance. The recommendations are focused on key areas, such as forming an industrial collaboration network, assessing predictive maintenance closely with other Industry 4.0 functionalities, and using a step-by-step approach.

The pharmaceutical industry is often highlighted as one of the industries that would highly benefit from a digital transformation. Transitioning toward industry 4.0 concepts policies and applications may allow processing a greater volume and variety of data toward better decision-making. Various industry 4.0 driven applications have emerged from this strong incentive. Predictive maintenance (PM) & equipment condition monitoring is not only of high interest within the pharmaceutical industry but also offers a strong incentive for applications that could potentially reduce production faults and production downtime. A digital transformation would enable the implementation of uninterrupted monitoring of equipment conditions during segmented process time periods. Currently, pharmaceutical manufacturing is mainly based on occasional offline monitoring of equipment conditions via pat (process analytical technology) equipment. This monitoring involves the monitoring of critical quality attributes. Equipment condition monitoring would add an additional level of insight to ensure that inline measurements from PAT do not trigger false production interruptions. In addition, better equipment condition monitoring would help to decide at which point equipment has to be pulled aside for maintenance and would therefore optimize (or better time) such a process to avoid production interruptions. Given the great amount of process data that has been historically collected, there is a need to explore the existing large pool of historical process and equipment data for potential uses in long-term equipment condition monitoring.

6. Future Trends and Innovations

The future trajectory of AI-driven predictive maintenance is explored in this section, with a focus on emerging technologies, trends, and innovations. To gain insight into the future of AI-driven predictive maintenance, a horizon scanning method is applied to identify current developments that could shape future systems [5]. This approach, often regarded as "future scanning", is widely used to augment foresighting capabilities by monitoring weaker signals of change, such as emerging technologies, innovations, social trends, and policy issues.

In order to observe the emerging landscape of AI-driven predictive maintenance, data about current developments was collected from publicly available sources. The new articles and reports were searched using specific keywords in different combinations: specific "maintenance" keywords (e.g., "predictive maintenance", "preventive maintenance", etc.) combined with "pharmaceutical", "medical", , "healthcare", "bio", "drug", "biotech". Here "pharmaceutical" is used as an umbrella term including traditional pharma plus biotech, life sciences, and so on. The resulting sample of 155 data points was analyzed and key themes/areas of activity were identified. These areas are subsequently elaborated upon in the following sub-sections; together they compose a picture of the emerging landscape of AI-driven predictive maintenance in pharmaceutical manufacturing [2].

6.1. Emerging Technologies

This subsection delves deeper into the emerging technologies that are poised to drive advancements in AI-driven predictive maintenance. It sheds light on innovative developments and technological trends that have the potential to revolutionize maintenance practices within the pharmaceutical manufacturing domain.

AI and Data Analytics Standardization: The availability of advanced AI solutions is enabling the emergence of industry standards for AI, data analytics, and machine learning processes in the pharmaceutical domain. Furthermore, efforts are underway to develop data standards for equipment, sensors, and processes to facilitate comparisons and benchmarking among AI efforts [2].

Digital Twins and Quantum Computing: As implementations of the digital twin facilitate the generation and collection of enormous amounts of data in the pharmaceutical industry, advances in AI techniques are anticipated to positively affect the number and capability of digital twins. Quantum computing is expected to significantly augment the capability of AI-based solutions. For example, the speed of Monte Carlo simulations can be increased by many magnitudes, allowing more complex systems to be simulated [5].

7. Conclusion and Recommendations

The drug manufacturing process in the U.S. pharmaceutical industry is a complex and expensive iterative manufacturing process that requires the use of large equipment sets and skilled and accredited technicians and scientists. This process is also highly regulated in terms of safety, efficacy, and time-critical. The U.S. pharmaceutical industry spends more money on enhancements and modifications for its drug manufacturing process than any other industry. Therefore, the effectiveness of production management systems for drug manufacturing, as they relate to process engineering, equipment engineering, and maintenance engineering tasks, is crucial to the economic success and social welfare of all Americans. The necessity of having a robust, cost-effective, and time-efficient drug manufacturing production management model has never been more obvious.

Pharmaceutical Quality Systems (PQS), computerized systems supporting the continuous manufacturing process, and the FDA's Quality Metrics Program exemplify the era of smart manufacturing in the drug manufacturing sector. Most of these advanced production technologies are based on decision assistance systems that apply predictive maintenance to the Industrial Internet of Things and Big Data scenarios. The paper presented a predictive maintenance model that uses differential diagnosis to generate predictive maintenance schedules for drug manufacturing production equipment based on the monitoring of both primary equipment condition and operating and environmental context that triggers biological or chemical degradation of machine parts leading to equipment malfunction. The paper's predictive maintenance model can help a drug manufacturing production management team's activities by educating them about pre-failure equipment condition and generating replacement times for parts and additional labor, as well as maintenance methods. The PM model's warning signals allow manpower management to organize preventive interventions that will guarantee continuous and effective remedial actions. Finally, the book also presents possible production efficiency enhancements for drug manufacturers that take advantage of the skills of the production maintenance departments necessary to implement the PM framework.

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