Leveraging AI for Predictive Maintenance in Pharmaceutical Manufacturing: Enhancing Efficiency and Competitiveness in the USA

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1. Introduction to Predictive Maintenance in Pharmaceutical Manufacturing

Industrial manufacturing represents one of the largest sectors in the USA, contributing approximately $2.25 trillion to the GDP in 2022. By utilizing an intelligent manufacturing operation, manufacturers can enable the automation of manufacturing processes, improve product quality, and enhance facility utilization. With access to historical production datasets through various sensors deployed into manufacturing facilities, Artificial Intelligence (AI)-based digital transformation technologies become accessible to industrial manufacturers. Applying AI-based technologies to enhance the efficiency of existing manufacturing facilities is known as AI for manufacturing, while developing AI technology for manufacturing systems is known as manufacturing for AI [1].

Processes for pharmaceuticals, adjuncts, and other sensitive components are heavily automated and standardized, minimizing human interaction. However, due to their batchwise nature, these processes steer away from continuous production. This still leaves room for non-linearities, seen as plausible causes of different outcomes in the final product. A predictive maintenance (PdM) approach was implemented, aiming to monitor unmeasured equipment conditions by means of product quality. To do so, the relationships with past successful output batches, collected through production monitoring systems, were processed with different time-delay artificial neural networks (TD-ANN). Also, a wider process and product quality analysis was launched using the Fisher test, retaining data used in the models for possible monitoring in future batches, while limiting false alarms [2].

1.1. Definition and Importance of Predictive Maintenance

Predictive maintenance utilizes new and traditional techniques such as hierarchical approaches, analytics, and machine learning (ML) algorithm applications [3]. Predictive maintenance denotes monitoring and analyzing the condition of an asset in real-time (or nearreal-time) to facilitate asset observability. A primary objective is to enable data-driven decisions for conducting maintenance beforehand failures occur or operate assets effectively despite detected issues. The pharmaceutical industry is a steadily growing industry in the USA and across many parts of the world. However, it can be hindered by equipment failures that could disable pharmaceutical processes. Downtime in pharmaceutical equipment operation can mean that production output of pharmaceutical products is insufficient to meet market demand. This deficiency in production output can cause economic losses or endanger human life if a pharmaceutical product is critical, such as vaccines, anticancer drugs, and life-supporting drugs [4]. Ultimately, competitive disadvantages against rival pharmaceutical manufacturing firms are another cause of concern.

Pharmaceutical manufacturing is unique compared to other sectors of the manufacturing industry. The pharmaceutical industry typically manufactures one-of-a-kind, high-value, low-volume products (also known as batch production) where a pharmaceutical product is produced in batches. One batch production might take hours to a few days or weeks. A batch of the active pharmaceutical ingredient has an estimated value of millions of dollars. A pharmaceutical ingredient is in a solid state; it cannot respond to and recover from failures, and a failure such as pump blockage may render a batch unusable. Current state-of-the-art predictive maintenance techniques require continuous data points to model the sequence of data points over time. These approaches typically cannot model unique assets producing unique, one-of-a-kind products due to insufficient continuous multivariate data collected over time. Emerging technologies, such as Artificial Intelligence (AI) and ML, provide further opportunities for improving equipment performance in predictive maintenance endeavors. Such technologies are gaining more attention as there is a growing realization among the service industries, including various manufacturing industries, that they may have competence in the core product the firm can manufacture but not necessarily have superior knowledge and assets in sustaining and maintaining equipment reliability.

2. AI Technologies for Predictive Maintenance

Artificial Intelligence (AI) encompasses computer systems that can perform tasks typically requiring human intelligence, including perception, reasoning, and learning, often drawing inspiration from the understanding of intelligent behavior in the human mind [1]. The earliest AI systems were knowledge-based, employing rule systems to encode human expertise and inform computer decisions. However, due to the reliance on human knowledge, this approach was slow and costly. The arrival of the "Big Data" era led to the advent of "data-driven" AI, which automatically builds models through computer learning from data, reducing reliance on human knowledge [5]. The use of large and diverse data for model training enables AI to discover complex patterns and behaviors beyond human understanding.

AI developments led to the emergence of deep learning (DL), which imitates brain neurons' functioning through artificial neural networks (NN). Deep NNs, capable of processing multiple levels of data abstraction, have driven rapid progress in perception applications such as natural language processing, image classification, and game-playing. The combination of advanced machine learning (ML) techniques and massive amounts of data has significantly improved models' performance in many applications, including pharmaceutical manufacturing.

Although traditional predictive maintenance approaches are efficient in detecting faults, their detection and decision-making capabilities can be improved using AI-based methods. AI models can utilize data collected by sensors, enabling data-driven predictive maintenance. Data-driven approaches do not require the understanding of physical systems and rely solely on historical data. Data-driven models can learn patterns from past failures and are classified into statistical methods, machine learning, and deep learning approaches.

2.1. Machine Learning Algorithms in Predictive Maintenance

In the realm of predictive maintenance, the spotlight often shines on machine learning algorithms. For the uninitiated, machine learning is AI's branch, modeled on our brain's neural networks. AI technologies are generally categorized into three branches: rules-based systems, expert systems, and machine learning. Machine learning is bifurcated into supervised learning and unsupervised learning. Supervised learning entails feeding the system data records with existing labels/classes to identify novel patterns and outcomes from non-labeled dataset records. In contrast, unsupervised learning identifies naturally existing classes from a dataset void of labels or classes. The collection of clusters can subsequently be employed in predictive analytics. For instance, utilitarian data like running time, pressure, and flow can elucidate a pump's operating behavior class, whether benign or faulted, thereby anticipating probable failure and active preventive measures [5]. In the context of predictive maintenance, a supervised approach is typically adopted.

Technologies facilitating predictive maintenance include machine learning (ML), the Internet of Things (IoT), and cloud computing (CC). Collectively termed IT3, the convergence of these technologies has revolutionized the ability to perform predictive maintenance in situations previously deemed impossible [6]. The aforementioned technologies are presently at the disposal of major corporations. Nonetheless, small and medium enterprises are largely incapable of capitalizing on the derived benefits due to resource constraints. Therefore, the time has come to offer predictive maintenance as-a-service, enabling small and medium enterprises to harness the advantages of predictive maintenance.

3. Challenges and Opportunities in Implementing AI for Predictive Maintenance

The implementation of AI for predictive maintenance in pharmaceutical manufacturing presents several challenges hindering data accessibility, quality, and human resources. Issues disruptive to effective data sharing include incompatibility of organizational standards or platforms for data collection, storage, and sharing. Adding to this issue, ensuring quality and integrity within the data sets is compounded by the data sharing itself. Pharmaceutical manufacturing facilities regularly hold both product and corporate proprietary data, and companies may thus shy away from full disclosure of sensitive data unit operations or extensive sharing of long-term data processing [1]. Relatedly, upper management must create a team structure that fosters collaboration between departments, permitting the building of multi-disciplinary teams with the specialized skills necessary for data evaluation and the development of AI tools/algorithms.

Despite challenges, adopting AI for predictive maintenance presents exciting opportunities for improving the efficiency of manufacturing facilities while increasing competitive player standing in the pharmaceutical industry landscape. Companies can help ensure the outlook of a more supportive manufacturing landscape in the USA, assisting in restoring and broadening national pharmaceutical production, in agreement with recent pharmaceutical manufacturing regulatory incentives. Additionally, with AI tools employed in predictive maintenance, national manufacturing facilities stand to benefit from reductions in equity than the reliance on human-based maintenance assessments. The human-based workforce is unlikely to be a scalable workforce in regards to both growing and operating facilities and the.

In a climate looking towards more safety and particularly disaster preparedness, AI predictive maintenance assists plants in reducing time-to-answer in comparison to the current human assessment-dependent paradigm, enhancing mitigation efforts and dramatically reducing equipment downtimes when undergoing hazardous failures [7].

3.1. Data Quality and Accessibility Challenges

A prerequisite for implementing AI is the availability of high-quality data, which is often required to build accurate models. The most common problem faced when ramping up AI is not an absence of data, but rather an abundance of unused data that is of unaccustomed quality [8]. This data can be either inaccessible, such as data stored in closed systems without an API, or it can take on myriad formats that complicate the automatic execution of processes. Although some ready-to-consume datasets exist both for research and commercial purposes, they provide either only a basic set of features or do not fully reflect the complexity of the world. Whereas it is possible to invest in the establishment of simpler AI solutions, such as expert systems that use information provided manually by the user, more complex AI applications, such as predictive maintenance, assume a larger variety of automatically acquired data.

To achieve successful AI integration, high-quality production data is key. Not only does it require a broadened view of the nature of the data, but it also calls for the consideration of critical prerequisites for the establishment of reliable datasets for modeling and validation. In pharmaceutical manufacturing, which is dominated by high-value products, unexpected production stops are both more challenging to account for and more costly than in industries where the opposite is true. This ensures a rich environment of historical production data available for analysis. Hitherto, however, any attempts at utilizing this data pool in advanced analytical applications have been chiefly descriptive in nature, highlighting time-consuming and intensive efforts to develop methodologies that harmonize data [2]. Key data quality and accessibility issues that need to be addressed to embark on the establishment of such an AI application are discussed.

4. Case Studies and Best Practices in AI-Driven Predictive Maintenance

A data-driven approach for long-term condition assessment of the equipment utilized in sterile drug product manufacturing is proposed. A previously available data set was analyzed and additional batch monitoring data from an equipment of interest was collected. Within this context, equipment failures and underlying deteriorations steadily progressed over time.

Regression models to recognize underlying process deviations were developed and wearable sensors were deployed on the investigated equipment. Obtained results indicate that batch monitoring data can be used for long-term condition assessment of the analyzed compounding equipment in pharmaceuticals. Data aggregation to a common batch time index allows for an initial investigation of a large variety of parameters [2].

In addition, a batch time index aggregation approach for the implementation of a wear monitoring filter system in this manufacturing environment is proposed. Using undertaken data preprocessing steps as a basis, additional wear monitoring metrics are investigatively applied. Their efficacy in recognizing process deviations before the failure acts is validated in thorough case studies, establishing promising directions for ongoing and future evaluations. A successful predictive maintenance solution can be established by complementing the metrics identified with the numerical simulation of the wear process [1].

4.1. Success Stories from Leading Pharmaceutical Companies

Bristol-Myers Squibb (New Jersey, United States). Advanced process control (APC) and predictive maintenance are two key digital technologies initially deployed for the drug substance secondary manufacturing value stream of an oral solid dose facility in 2017 to control and optimize a wet granulation process [2]. The success of the innovative PDE technology has led to interest in the expansion of its scope to other processes. Of these, a predictive maintenance solution with a need for additional equipment and development support was identified as the priority. Data from two process and one non-process equipment were onboarded into the data hub with the support of the corporate engineering team.

A total of 2,632 alarms from the two wet granulation processes were analyzed. Some 54% of them affected both manufacturing lines. Further analysis showed that the higher alarm rate of line 1 was due to a combination of improper equipment specification, line configuration & usage, and perceived underlying issues with the specific equipment. Drawing on these success stories, key learnings and best practices have been compiled to inspire and guide similar efforts targeting ROI handling capabilities [1].

5. Regulatory Considerations in AI-Enabled Predictive Maintenance

The work explores the regulatory considerations surrounding FDA compliance regarding the use of AI for predictive maintenance and evaluates the impact of leveraging AI technologies to improve predictive maintenance compliance and thus enhance competitiveness. The pharmaceutical industry is one of the most regulated industries in the world, given that its products make important claims regarding life and health.

Pharmaceutical manufacturers are thus heavily regulated by the FDA, a government agency that is tasked with ensuring the safety, efficacy, and quality of pharmaceuticals. To achieve that, the FDA has established Guidance Documents and regulations that need to be complied with [1]. Failure to comply with FDA guidelines and regulations can lead to the imposition of large fines, criminal convictions, and the shutdown of the facility. This is why it is paramount for manufacturers in the pharmaceutical industry to understand the compliance obligations and how they can be achieved. These compliance challenges are accentuated by the introduction of novel technologies such as Big Data, Cloud Computing, and AI, which can fundamentally change the way that manufacturing is approached in the industry and how the underlying data is managed. The regulatory considerations regarding the use of AI are understood by understanding FDA compliance regarding the collection and use of data [5].

5.1. FDA Guidelines and Compliance

For AI-enabled predictive maintenance applications, compliance with FDA regulations and guidelines concerning the equipment and facilities used to manufacture drugs is vitally important. Current guidelines are interpreted and compliance factors that govern the development and use of AI applications in maintenance are discussed. This concerns especially the development of process digital twins and AI models that analyze data for use in AI digital twins [2]. Since AI models often change over time – for instance, as the facilities they analyze change or as new information like maintenance logs and replaced equipment are added – it is foreseeable that compliance with FDA requirements, such as those of Title 21 Part 820 (Quality System Regulation) or Part 11 (Electronic Records/Electronic Signatures), needs to be maintained not only for the AI model's development process but also during its operation. Furthermore, even with the updated 2022 Draft Guidance for Industry: Computer Software Assurance for Manufacturing, Operations, and Quality System Software, compliance to FDA guidelines for AI applications needs to be treated differently than classical automation systems, which can have profound implications for how facilities are designed [1].

6. Future Trends and Innovations in AI for Predictive Maintenance

Advancements in Artificial Intelligence (AI) technology will continue to drive the development of predictive maintenance in the future. Future trends and innovations in AI for predictive maintenance, particularly in pharmaceutical manufacturing, are discussed with a focus on the integration of Internet of Things (IoT) and AI technologies. IoT devices such as sensors, cameras, and drones are increasingly used to gather data related to asset condition, production processes, and environmental factors. AI algorithms like image recognition and deep learning can analyze visual data to monitor pharmaceutical facilities, detecting issues like contamination, equipment wear, or parameter deviations. Similarly, AI models can analyze environmental data from IoT sensors to predict equipment wear, breaches in cleanroom microclimate, or raw material deterioration [1].

Moreover, AI-powered digital twins, which are 3D virtual replicas of assets or manufacturing processes, could be used for advanced simulations based on real-time data from IoT systems. Engineers would prototype new production scenarios in the digital world before implementation, optimizing process time, energy consumption, and other KPIs while maintaining product quality and safety standards [5]. AI technologies can increasingly support and automate maintenance workflows, including risk identification, prioritization, and implementation of maintenance actions. In conclusion, the field of AI in predictive maintenance is rapidly evolving, particularly with the growing importance of IoT technologies and their integration with AI algorithms and methodologies.

6.1. Integration of IoT and AI Technologies

The Industrial Internet of Things (IIoT) is an evolution of IoT technologies applied to industrial operations and environments. IIoT can connect sensors, devices, machines, and humans to capture and analyze most activities, workflows, operations, and conditions in industrial environments, and make better and smarter decisions. The use of the IIoT is revolutionizing the industrial landscape, as more companies are willing to and adopting this technology. The application areas of the IIoT are broad, including track and trace, quality assurance, operational data analysis, big data, artificial intelligence and machine learning analytics, process automation and enhancement, asset management, and predictive and prescriptive maintenance. This paper proposes usage and a pilot implementation of the IIoT to achieve predictive and prescriptive maintenance in flexible manufacturing systems (FMSs), a topical field and a complex task that has not been widely achieved before [9]. Research challenges and a future research plan are also discussed.

Predictive maintenance (PdM) strategies can support the manufacturing industry to become more efficient and competitive. Currently, there exists an increasing amount of sensor data that reveals the current conditions of the production tools. Detecting patterns from this data and applying these patterns can address PdM strategies. Advanced technologies based on the combination of Artificial Intelligence (AI) and Data Mining could be utilized to achieve these strategies. All these Data Mining techniques that can handle big data predictive maintenance (PdM) can create a research area between AI and IIoT [6].

7. Conclusion and Key Takeaways

The application of AI technologies, such as predictive maintenance, smart maintenance, and self-monitoring systems, plays a crucial role in establishing Industry 4.0 smart factories within the pharmaceutical sector in the USA. It fosters collaboration among universities, research centers, small and large companies to overcome challenges like pollution and pharmaceutical product shortages. AI predictive maintenance technology empowers pharmaceutical manufacturing companies to address equipment failure issues and enhance efficiency and competitiveness. This technology identifies and assesses critical equipment failure parameters, determines optimal maintenance strategies, and develops appropriate AI algorithms for successful decision-making and cost-effective implementation.

Integration of AI predictive maintenance technology in pharmaceutical manufacturing facilities is imperative for compliance with government regulations on safety, product quality, and data protection. The adoption helps to improve yield, limit production downtime, curtail unscheduled maintenance expenditures, and strengthen pharmaceutical supply chains. Nevertheless, its implementation and extensive adaptation is still in the infancy stage within the pharmaceutical manufacturing industry in the USA. Academic and market studies would be conducted to thoroughly analyze and evaluate the current condition of AI in the pharmaceutical manufacturing sector.

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