# The Role of AI-Based Predictive Maintenance in U.S. Pharmaceutical Manufacturing

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## 1. Introduction to Predictive Maintenance in Pharmaceutical Manufacturing

Adverse events can arise as a result of human errors, equipment failures, power outages, etc. in every production plant, causing heavy monetary losses. This is especially true for FDA-regulated pharmaceutical companies, where batch production losses can amount to hundreds of thousands of dollars or more if any critical product attribute is compromised and requires reprocessing or destruction [1]. In addition, plants also suffer from minor faults that lead to unscheduled equipment downtimes. Although individually less grave, they aggregate to substantial product loss over time and can potentially trigger a chain of events resulting in larger failures. As production capacity grows, assets require more maintenance and thus generate a greater amount of data. This data can be analyzed in order to gain insights regarding long-term equipment condition and develop data-driven predictive maintenance applications to facilitate timely failures. However, it has yet to be explored how the investigating methodology must be adapted to fit the challenges of sterile drug product manufacturing.

The pharmaceutical industry is undergoing major changes with respect to digitalization and automation, promising a more patient-centric production and better assurance of product quality. As part of this development, AI has the potential to revolutionize Pharmaceutical Manufacturing. This paper explores how AI can have a positive impact and what restrictions must first be overcome [2]. Currently, the application of AI in pharma is still in its infancy. Several noteworthy advances have been proposed in the literature, from drug discovery and design to clinical trials using reinforcement learning. However, there is still a lack of practical AI applications that have been implemented in the industry. There appear to be numerous constraints, both from the technological and cultural sides, preventing a greater uptake from taking place. In order to facilitate and accelerate the AI adoption in pharma, an understanding of what is happening is required as taking a wait-and-see approach is not an option in an increasingly competitive environment.

**2. Fundamentals of AI and Machine Learning in Predictive Maintenance**

Artificial intelligence (AI)-based predictive maintenance integrates AI and machine learning with maintenance strategies and uses predictive algorithms to define maintenance plans and schedules, which avoid unexpected failures while minimizing costs. Early examples date back to 1986: AI tools for predictive maintenance were developed under the coordination of NASA to estimate the need for maintenance and repairs of satellites. Today, AI tools for predictive maintenance are becoming a reality in various industries. By continuously analyzing data from sensors and other sources, these tools can indicate the occurrence or likelihood of faults or defects before they happen. Once the data suggest that a machine is developing a problem, notifications can be sent, and actions like preventive maintenance or stopped operations can be taken [3].

As pharma manufacturing equipment presents high capital costs and unexpected break-downs costs due to production interruptions and product losses, pharmaceutical plants can significantly benefit from predictive maintenance to avoid unexpected breakdowns. This vastly reduces the overall maintenance costs and increases the longevity of the pharmaceutical plants' equipment. Another trend is the growing regulatory requirements for traceability along the whole manufacturing batch process. Data used for Quality by Design (QbD)/process analytical technology (PAT)-based and AI-based process monitoring and optimization need complete and correct documentation of the manipulated equipment, the used raw materials, and the computational and result logs [2].

**3. Challenges and Opportunities in Implementing AI-Based Predictive Maintenance in Pharmaceutical Manufacturing**

Addressing the complexities of implementing AI-based predictive maintenance, this section identifies key challenges and opportunities associated with the integration of AI in pharmaceutical manufacturing settings. It offers a balanced perspective by outlining the potential benefits while acknowledging the hurdles that need to be addressed for successful implementation. This provides a realistic view of the landscape and prepares stakeholders for the intricacies involved in leveraging AI for predictive maintenance.

AI-based predictive maintenance has the potential to create enormous value for pharmaceutical manufacturing. However, organizations face challenges implementing and integrating it into their businesses. To better understand which challenges these organizations face, a scoping review was conducted. It identified 16 relevant AI-based predictive maintenance challenges, which were grouped into four main challenge categories: process-related, data-related, technology-related, and socio-technical challenges. In addition to challenges, various opportunities were identified. Two main AI-based predictive maintenance opportunities emerged: creating a new business segment within pharmaceutical manufacturing and increasing competitiveness and compliance with regulations [1].

Pharmaceutical manufacturing helps ensure products' required quality, recommended dosage, and good manufacturing practice compliance. Current pharmaceutical manufacturing practices often use time-based, calendar-based, or usage-based maintenance strategies, which do not consider the equipment's actual state [2]. AI-based predictive maintenance aims to replace this with data-driven prediction models that provide information about potential equipment failure states in advance. Despite the intensive capital investments, the potential of AI-based predictive maintenance has not yet been realized in pharmaceutical manufacturing, leading to expensive non-scheduled downtime. Failures are most often detected after the fact, and attempts to forecast a failure or its root cause often do not exist. Recent developments, such as digitalization, Industry 4.0, and the increased use of IoT and connected devices, could provide new data-driven opportunities, taking into account the current manufacturing trend towards continuous and more complex processes.

## 4. Real-World Applications of AI-Based Predictive Maintenance in Pharmaceutical Manufacturing

Focusing on real-world applications, while previous sections discussed AI-based predictive maintenance technologies/tools, research gaps, and suggestions to close the gaps, this section demonstrates AI-based predictive maintenance use cases. Use cases provide insights into pharmaceutical manufacturing maintenance needs that AI technologies have addressed. Certain AI tools have been effectively utilized to solve maintenance issues in pharmaceutical manufacturing, providing a good understanding of relevance and impact in the industry. Recent publications from the literature describing AI-based predictive maintenance applications in pharmaceutical manufacturing are summarized. Examples of specific AI technologies/tools deployed to tackle specific maintenance challenges are also included. Case studies shed light on the practical aerospace manufacturing industry experiences of AI-based predictive maintenance implementation and lessons learned. In addition, the coverage of pharmaceutical manufacturing activities from these case studies is highlighted. As a result, this section demonstrates the real-world application of AI-based predictive maintenance in pharmaceutical manufacturing and supports the importance of this study area [2] ; [1].

**4.1. Case Study 1: Predictive Maintenance for HVAC Systems**

A detailed case study based on actual AI-based predictive maintenance established for Heating, Ventilation, and Air Conditioning (HVAC) systems in a U.S. pharmaceutical company is presented. Heating, ventilation, and air conditioning (HVAC) systems are critical infrastructure in pharmaceutical manufacturing processes and need to be routinely monitored and maintained to ensure compliance with government regulations. However, similarly to other industries, scheduled maintenance among heating, ventilation, and air conditioning (HVAC) systems in a pharmaceutical facility is not ideal, resulting in equipment breakdown or deterioration in product quality. To address this challenge, AI-embedded predictive maintenance was developed for monitoring chiller units, air handling units (AHUs), and temperature and humidity sensors. Available datasets encompassing the past five years of operational data were utilized. Maintenance work orders were generated in response to chiller alarms, AHU temperature dew point status, and zoned room temperature and humidity status, which were considered as failure events. Crankcase heaters before and after the compressor was identified as a failure of chiller units, while chilled water valve status (stuck open and closed) was identified as a failure of air handling units. By focusing on chiller units, air handling units, and temperature dew point sensors, AI-based predictive models were developed based on long short-term memory (LSTM) neural networks. Predicted probabilities for failure events of HVAC systems were generated based on these AI-based predictive models [4].

Accordingly, chiller units, air handling units, and temperature dew point sensors were identified as failure events that can generate a work order for maintenance to be performed. A dashboard was created for visualization that compares historical probabilities with a run-time operational dataset. This enables plant operators to easily identify which equipment and sensors need to be inspected and their remaining time before failure [5].

### 4.2. Case Study 2: Predictive Maintenance for Production Equipment

AI-based predictive maintenance is in active use at a pharmaceutical manufacturer in the United States as a complement to existing maintenance strategies. Focused on production equipment, this case study illustrates a second dedicated use case for AI vs. a more general overview of other AI applications. The existing maintenance approach is labor intensive and reactive, responding to signs of failure via unplanned downtime, and costly due to replacement part, overtime, and production loss expenses. The AI-based application replaces this manual and time-consuming approach with an automated one leveraging equipment condition data and modern machine learning tools. Challenges met in this AI implementation include gathering and preprocessing data, optimizing the AI model against domain expert expectations, drafting a communication plan, and fostering user adoption via interface design [4]. Broad takeaways on the themes of implementation and use case pivot approaches complement and strengthen learnings from the previous dedicated predictive quality use case.

Despite the potential benefits of AI, the pharmaceutical industry has been slow to adopt it. The historical data commonly leveraged for AI applications are system generated and not human created. Consequently, the pharmaceutical industry's pool of historical data ought to complement its conservative approach to regulatory innovation [1]. Hence, the ability to successfully sidestep this bias via an automated AI approach is arguably shaped by the complex regulatory environment the industry operates in, driving a persistence and demand for robust AI solutions.

## 5. Key Technologies and Tools for Implementing AI-Based Predictive Maintenance

AI-based predictive maintenance systems rely on a variety of technologies and tools to analyze data from sensors installed in machines. These systems can establish correlations and predict the future behavior of various functions. Once a system is in place, knowledge discovery can be applied to natively available data to detect the first warning signs of deteriorating machine conditions. The system can also be adjusted and optimized based on the operational experience gained.

The basic components of an AI-based predictive maintenance system consist of hardware (sensors, a communication network, and cloud/edge and computer resources) and software applications. Requirements for each component are very much dependent on the type of equipment under consideration, the context of its operation (whose decisions to support, e.g., from machine vendors, or machine operators), and the particular business goals (e.g., the maximum expected failure time for equipment or the trade-off between expectations on the return on investment and the risks on reputational loss) [1].

**6. Data Collection and Preprocessing Strategies for Effective Predictive Maintenance**

To explore the potential and opportunities of AI-based predictive maintenance systems, a focus on the data management aspects is essential, as all aspects of intelligence systems start with data. Addressing data management requirements, this section covers the underlying strategies for collecting data and preprocessing data in a way that enables effective predictive maintenance. After a discussion on the significance of quality data, the preprocessing techniques needed to ensure the data is effective in the context of predictive maintenance implementation are addressed.

This address to the foundational aspects of data management aims to present an overview of the strategies and methodologies needed to successfully harness the data needed for predictive maintenance [1]. Although a wide range of approaches exists for data interpretation in the context of predictive maintenance, almost all methods rely on data. It is thus of utmost importance to ensure a strong foundation for AI-based predictive maintenance system implementation by managing the data in the right fashion.

The intention of this discussion is not to provide an exhaustive overview of the different approaches to data collection and preprocessing, as this would be outside the possible scope [6]. Taking inherent process and organizational factors into consideration is of great importance when choosing the most appropriate route, as each individual pharmaceutical manufacturing facility has its own unique combination of setups.

**7. Model Development and Evaluation Techniques in AI-Based Predictive Maintenance**

Data in phyto-nutraceuticals should be mean normalized and centered; additionally, data should be filtered to remove "rippler" effects due to automobile temperatures variations in cars and to remove outliers (values greater than 3 standard deviations). Data should be divided into learning (training) set and validation set, and tendentially no more than 30% of data should be used for validation. Artificial neural networks should be trained with randomly generated initial synaptic weights, to avoid starting in a local minima, and the initial weights may be scaled according to the number of inputs and outputs. Training neurons transfer functions should be sigmoid-type, with caution on using the hyperbolic sigmoid due to possible numerical difficulties. Network architecture should preferably obey the multiplicative effect of δ and α, trying combinations of architectures until 13 subnets calculated or duration for epoch is lower than 5000, and the structure of networks should avoid architectures where the number of hidden neurons is higher than the number of inputs. Neurons in hidden layers should provide sufficient (mean), in the first hidden layer, between 2 to 5 hidden neurons per input, contemporary filtering the number of hidden neurons according to model complexity (rms error) and results of simple linear models (as Bayesian estimation or PLS). Neurons in the hidden layers have to provide sufficient (mean), in the last hidden layer (the output layer), 1 hidden neuron per output [3]. Adam is full of hyper-parameters but can default to the same as RMSprop, with $\beta1 = 0.9$, and $\beta2 = 0.999$, and $\varepsilon = 10{-}8$. Adam represents an algorithm for first-order gradient-based optimization of stochastic objective functions, based on adaptive estimation of first and second moments of the gradients, being highlighted for fast convergence.

**8. Integration of Predictive Maintenance Systems with Existing Infrastructure**

Focusing on the practical aspects of implementation, this section explores the integration of AI-based predictive maintenance systems with the existing infrastructure within pharmaceutical manufacturing facilities. It addresses the challenges and considerations associated with seamlessly incorporating AI-driven maintenance systems into established facilities, offering valuable insights into the operational aspects of integration. Notably, representatives from CPOs, OEMs, and pharmaceuticals would be beneficial to facilitate discussion on common concerns throughout the facility, including the sanitary environment and shared control systems, which are vital for the integration of existing manufacturing equipment and instruments into the host system. There is also a special focus on papers supporting the technological value of artificial intelligence while also investigating the largely overlooked horizontal aspects of such AI systems [7].

The pharmaceutical industry strictly adheres to regulations and standards pertaining to documentation, monitoring, equipment fit-for-purpose, and maintenance regimes, among other variables. These elements should be aligned with existing protocols for artificial intelligence-based predictive maintenance implementation or risk running afoul of regulatory or corporate policies. For example, will new algorithms that approach maintenance as a fraction of the lifetime rather than the absolute numbers used in most current offerings? As AI and edge technologies proliferate, sharing information straight from the manufacturing floor to the cloud may be more attractive than storing and processing it locally [3].

## 9. Regulatory and Compliance Considerations in AI-Based Predictive Maintenance for Pharmaceutical Manufacturing

The application of artificial intelligence (AI) and big data analytics has gained tremendous impetus in recent years. The ideas of e-manufacturing and 'Industry 4.0' provide new opportunities to improve the completeness and productivity of pharmaceutical facilities through smarter equipment monitoring and operations [1]. Pharmaceutical manufacturing is associated with high reliability and likelihood of 100% compliance to regulatory requirements. The existing strategies for monitoring and adjustment of equipment health in the industry, however, are rather challenging, given the historical focus on complying with regulations primarily based on activities or events. For pharmaceutical manufacturing facilities, the implementation of the international standard, Good Manufacturing Practice (GMP), is mandatory to ensure product quality and patient safety. During the process, e.g. validation, registration, and periodic evaluation of any adjustment changes within the facility, equipment, or processes were required [2]. This has led to veering on the side of caution, with issues arising from technologies being overlooked or discarded altogether due to being "not GMP-compliant".

The management of equipment health with an AI and big data-driven approach could be of great benefit to pharmaceutical manufacturing. It might enable the transition to a paradigm of compliance with real-time process performance data and near-time information regarding equipment process history, condition, and impending faults. With this transition, smart and efficient operations of the pharmaceutical manufacturing facility may be accomplished. However, various considerations and compliance to a wide range of regulations and legal requirements were needed before AI-based maintenance practices could be established. Compliance to regulations is related to the organization of rules, plans, or principles and is used in various contexts. It is also used with a focus on the adherence or observance of legal frameworks, standards, and guidelines which must be accounted for when AI-based maintenance practices are to be established. For computer software, compliance refers to the adherence to such laws and ensuring that the consequences of running a program or system fully or partially (i.e. in adherence) fulfilling its requirements since "non-compliance" might render the program or system illegal with legal actions taken against its user or operator.

**10. Future Trends and Innovations in AI-Based Predictive Maintenance for Pharmaceutical Manufacturing**

As AI-based predictive maintenance further matures and gains traction, several trends are anticipated to shape its evolution in U.S. pharmaceutical manufacturing. These trends include the development of more sophisticated machine learning algorithms, such as multi-task learning and transfer learning. These methods can leverage multi-sourced data more efficiently, improving predictive maintenance performance and reliability. More explainable AI-based predictive maintenance models are expected to be developed to better elucidate the rationales of their predictions [3]. Several interpretability models exist today, enabling transparency in both data-driven and physics-driven AI approaches. Such interpretable approaches can help pharmaceutical manufacturers build trust in predictive maintenance solutions, as well as ensure compliance with regulations from agencies like the FDA. The integration of AI-powered predictive maintenance models into advanced manufacturing systems, along with the data-enabled digitalization of assets, continuous data acquisition, and implementation of IIoT technologies, are expected to accelerate in the coming years [2].

Additionally, these models are predicated on proprietary algorithms developed within the company and are embedded in existing legacy systems. AI-based predictive maintenance models can be integrated into a hybrid framework that includes both on-premises and cloud-based elements. This architecture would connect on-premises manufacturing resources, including sensors, machines, and devices, through secure gateways linked to centralized cloud platforms for data storage, processing, monitoring, visualization, and control. There is also expected to be a surge in AI-based software solutions targeting predictive maintenance in pharmaceutical manufacturing. Currently, AI-enabled predictive maintenance is an emerging and competitive field in pharmaceutical manufacturing, with innovative solutions being developed by startups and large corporations alike. Thus, there is a rich opportunity for pharmaceutical manufacturers to explore commercial AI-based predictive maintenance offerings in other sectors and analogous research in their target industry.

### 11. Conclusion and Recommendations for Successful Implementation

To ensure the completion of maintenance on all critical equipment is completed efficiently, pharmaceutical manufacturers in the U.S. are considering the use of an AI-based predictive system to suggest the right action to take. With a real-time, actionable AI recommendation, potential ability to shift from PM to predictive PM at some level of maintenance cost increase, AI will bring ROI. According to McKinsey & Company, for an AI model, there's no ROI unless there is a need, or an opportunity cost less the cost of the necessary changes.

The real value of using AI to execute maintenance is making the tool thought of as 'intelligent,' thereby changing the maintenance decisions in real-time with no surprises. AI for maintenance is relatively easy — sometimes too easy — but AI does solve the maintenance problem when done correctly, and remaining flexible is a requirement. For the time needed to use AI for ongoing decision making, AI changes the problem of implementing maintenance solutions with less than optimal strategies. Using AI for both real-time monitoring of equipment health and execution, solving the problem is a win-win. Considering inspection data, waiting for precise information to know what to do, providing virtual support, and relying on big data and AI for critical field plant equipment will greatly reduce the maintenance costs. Maintaining the earnings of the company when meeting regulatory requirements and increasing occupant safety, stopping the gap that's what pharmaceutical executives face frequently when it comes to maintenance. Preventive maintenance for pharmaceutical manufacturing facilities is big business, with the size of the laboratory and production sites, as measured by the number of employees, in the largest companies. With such flourishing operations, all production sites must run as effectively as possible to ensure that its sustainable growth is always included.

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