

Original Article

# Database-Driven Optimization of Production Line Downtime in Pharma Manufacturing Using Hierarchical Models

Srikanth Reddy Katta<sup>1</sup>, Sudheer Devaraju<sup>2</sup>

<sup>1,2</sup>Independent Researcher, USA.

Received Date: 07 October 2021

Revised Date: 10 November 2021

Accepted Date: 08 December 2021

**Abstract:** One of the major issues drawn from manufacturing production lines in the pharmaceutical industry is time loss due to production line halts. Effective downtime management must be supported by a powerful solution that involves information analysis and sophisticated optimization tools. This research work considers a database-oriented solution based on the use of hierarchical models with a view to analyzing and tracking production downtime. To categorize downtime factors into different levels, a nested structure is adopted to obtain high levels of detail that would help identify the appropriate action to address each cause. Analyzing a large big data set, such as a large pharmaceutical plant data set consisting of machine performance details, production plan, and error report, some of the advanced techniques, such as regression analysis, decision tree, and optimization, can be used. The hierarchical model breaks down downtime into three major categories: This is a relative of planned maintenance, unplanned machine failures, and process inefficiencies. Probabilistic tools and forecasting models are used to analyze relations, identify the likely downtime profiles and recommend proper measures. Data available to the authors show that it is possible to achieve up to a 15 per cent decrease in OT and to raise OEE by 10 per cent. This approach enables timely decision-making through real-time data monitoring, prognostics, and health management. They emphasize the need to adopt a database-driven solution to enhance efficiency in the production processes of a pharma manufacturing plant to enhance output while at the same time cutting on time used for repairs and other customized tasks.

**Keywords:** Production Downtime, Pharmaceutical Manufacturing, Hierarchical Models, Machine Learning, Predictive Maintenance, Root Cause Analysis.

## I. INTRODUCTION

### A. Background and Motivation

Pharmaceutical production is a complex industry where it is very important to optimize operations. These disruptions stop manufacturing holistically, reduce the output rates of products, and raise operational expenses, which are undesirable. Assembly line downtime may be due to deliberate actions such as during maintenance, occasioned by equipment failure and due to inefficiencies inherent within the assembly process, which is a key consideration in any production line. [1-4] Pharmaceutical production lines are nowhere near simple lines and require a systematic and database approach for downtime. Downtime factors can be analyzed by following a logical background appearing in hierarchical models, which are straightforward in many-level analyses like root cause identification, prediction, and optimization. Downtime optimization has become even more feasible due to adopting Industry 4.0 technologies, including big data, analytics, and machine learning.

### B. Importance of Downtime Optimization

#### a) Enhanced Operational Efficiency:

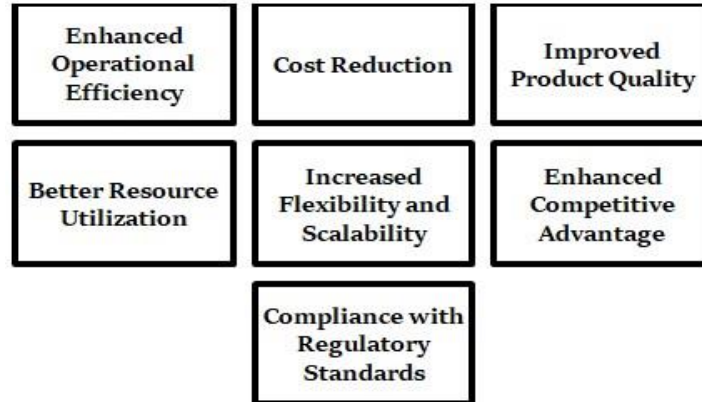
Thus, time maintenance downtime is a significant factor that contributes to increasing manufacturing processes' efficiency. Some operating downtimes include unscheduled uptime breaks or non-maintained time, random upsets, and equipment malfunctions, all of which impact the flow of production processes. Therefore, pharma production throughput, the amount of time available in a day and the number of days in a year for productive work is bound to rise, enhancing manufacturing effectiveness Line-wise in the pharmaceutical plants. This not only makes great use of available resources like equipment but also ensures that all the processes are done with greater efficiency. For example, those time targets and deadlines are met in production.

#### b) Cost Reduction:

Manufacturing always attaches high costs to unplanned downtimes because they are expensive in terms of production time and labor, most probably requiring costly repairs and replacements. These costs can be reduced, and pharmaceutical



companies can better manage resources through the optimization of downtime. Examples include predictive maintenance and preventive problem diagnosis, which assist in averting expensive repairs due to failures already overwhelming the system. Moreover, effective ways of using time cut down the cases of need for emergency treatments, which are normally expensive or demanding of resources. Less time means lower operating costs, thereby making the manufacturing process more efficient and, hence, making profits.



**Figure 1: Importance of Downtime Optimization**

*c) Improved Product Quality:*

Instances with extended or frequent downtimes tend to cause inconsistency in production and may, therefore, lead to the production of so-called substandard products. Whenever the machines or any particular process is not working efficiently, it results in production that is either off-standard, requires reworking, or is wasted. This allows the manufacturers to maintain optimum quality control compared to periods when they face lots of interruptions and, hence, lots of time that is not well utilized. Reducing time lost during production makes it easier to fine-tune the machineries and set standard operations in the manufacturing processes with little variance from the baseline, which are features that go hand in hand with high-quality production of pharmaceutical products that meet the desirable regulatory standards.

*d) Better Resource Utilization:*

He pointed out that the features of sound downtime optimization are directed towards efficiently using resources like labor, raw material and machines. Ideally, when working time is maximized, employees work more new time, hence being more productive, while equipment is utilized more. Also, improvements in planning enable the organization to plan and schedule maintenance activities to minimize downtimes at critical production times and, therefore, allocate its resources effectively. Pharmaceutical manufacturers can optimize the resources used in the production process to cut short wastage, enhance the flow of production, and eventually enhance value for money when it comes to investment in production types of equipment and human resources.

*e) Increased Flexibility and Scalability:*

Downtime optimization enables pharmaceutical manufacturers to increase flexibility in responding to new dynamics in production trends. Through low downtimes, it becomes easy for specific production lines to change the products they produce, alter the number of items being manufactured in each batch or even increase or decrease the production rate as desired. This flexibility is particularly well applied in the pharmaceutical industry because the production of pharmaceutical products is always tightly scheduled and can experience shifts in customer demand. Maximizing downtime also provides even control of capacity and the opportunity to promptly respond to other factors, including regulatory changes, new products or market trend shifts, enhancing long-term company development.

*f) Enhanced Competitive Advantage:*

Time, quality, and cost are the three drivers of value in a competitive pharmaceutical industry, and timely and efficient supply predicts competitiveness. As a result, the optimization of downtime is an incubator that directly shapes a company's capacity to meet such demands persistently. Manufacturers in a position to manage their downtime are likely to sustain productivity, reduce losses, and adapt to changing market trends. This is reflected in the quicker introduction of new products to the market, enhanced customer satisfaction, and improved competitive advantage for firms within the industry. Downtime

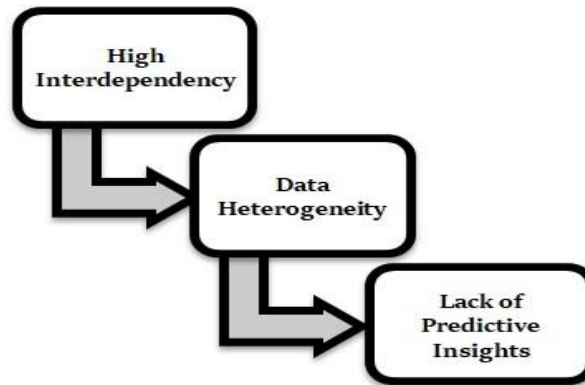
optimization, therefore, is not a purely organizational concept but is also concerned with an organizational edge over competitors.

g) *Compliance with Regulatory Standards:*

Pharmaceutical manufacturing is under the obligation to follow strict regulatory measures that ought to be followed throughout the manufacturing process. Time lost through line shutdowns makes it challenging to observe GMP and other regulations that they set. In this way, the manufacturers can manage to maintain a constant production line and avoid possible penalties or jams in their production line. In addition, optimization strategies, like the prediction of maintenance and continuous monitoring, provide exact records, traceability, and compliance audit support, limiting regulatory problems.

**C. Challenges in Downtime Reduction**

Since production lines in pharma manufacturing depend on each machine and system, causing much downtime, analyzing the causes is a challenging factor. [5-8] Existing methods, such as reactive maintenance and isolated analyses, are often insufficient due to the following challenges:



**Figure 2: Challenges in Downtime Reduction**

**A. High Interdependency:**

A particular feature of pharmaceutical production lines appears to be that connected machines and systems are usually heavily dependent on each other; this means that a failure in a given section of the line will fail the entire line. For instance, when a critical tool is unavailable, it can stop subsequent operations, and this will slow down the manufacturing process. This interdependency resembles the problem of identifying the precise causes of downtime since multiple machines and systems are affected. A problem in one machine may be an early sign of a more systemic problem or dramatically affect connected systems. Hence, it is impossible to identify the impact of downtime without knowing everything that occurs during production. Thus, traditional methods of isolating different segments do not work efficiently enough.

**B. Data Heterogeneity:**

It is crucial to have data from the manufacturing process in this field as the industry produces various forms of data, such as logs from factory machines and sensors, as well as reports on production processes and downtime events. However, These data sets can be heterogeneous in data format, structure, and frequency of data collection; a situation may cause complications in data amalgamation and analyses. For example, sensor data would present an instant picture of the condition of certain pieces of equipment. At the same time, production reports would provide a wider outlook on throughput ratios and utilization rates. Integrating these data sources in a coherent form is challenging, as the data sources are fragmented and disparate and require highly processed and sophisticated data processing and systems. When all the information is spread in this way, it is hard to notice patterns of future problems or make the right calls to prevent downtime.

**C. Lack of Predictive Insights:**

The more or less conventional ways of handling downtime are mostly rigid because maintenance or corrective actions are performed only after a failure. This is self-defeating because it generally results in long durations of system unavailability and costly fix processes. On the other hand, a predictive maintenance solution, which looks into future failures, can greatly help to decrease abnormal downtimes. However, the systems incorporated in the manufacturing of pharmaceuticals still have limited capability of predicting downtime events. This absence of forecasting knowledge hinders organizations from avoiding certain problems or situations. Thus, they continue utilizing ineffective reactive measures. To address this issue, there is a necessity for

consequent analytical models that will help to use historical data and monitor failures in real time to predict them and take action in advance.

## II. LITERATURE SURVEY

### A. Overview of Production Downtime

By its literal meaning, production downtime can be defined as any time during which the manufacturing equipment is not running and directly affects output, cost and overall efficiency. There are three broad categories of downtime. Scheduled other downtime means activities like repairs, modification and improvements that are expected and planned earlier in advance. [9-12] In contrast, unplanned downtime is unscheduled because it arises from one's failure to meet envisioned goals of machinery, equipment, or other systems, which may often be greatly disrupted. Inefficiencies are characterized by infections in a manufacturing process, be it in the organization of a process, the application of the process or even in the amount of time taken to execute a process without involving equipment failure but a hindrance to productivity. Every kind of downtime calls for specific strategies regarding its control and possibilities to minimize the impact of potential downtime.

### B. Traditional Downtime Management Approaches

Conventional downtime management techniques include manual reporting, which is more of a reactive way of managing the equipment and time to perform troubleshooting activities. These strategies usually involve the operators and maintenance personnel to notice and counter any problems as and when they occur. However, these tactics have logistic deficits, which include slow data feedback, non-real-time results, and improper use of resources. Since issues are addressed reactively, it tends to take longer for a system to be back up and running, productivity is affected, and maintenance costs are high. Moreover, the traditional approach could not solve the problems systematically. It could not use the data in a manner that would reveal future problems or the causes of their recurrence, which indicates a lack of efficacy in the long term.

### C. Database-Driven Analytics in Manufacturing

Database-driven analytics has emerged as one of the most crucial aspects in the new generation manufacturing thinking regarding reducing downtime and improving operation. These systems obtain, retain, and utilize enormous quantities of data from machines, sensors, and processes in real-time, allowing manufacturers to assess and discover inadequate operation processes comprehensively and immediately. Some examples include SQL databases, cloud solutions, and big data solutions that enable it to contain any size of data set and perform data analysis to create value-added insights. Real-time data analysis enables manufacturers to get alerts of anomalies or failures to prevent them from occurring or detect them at an early stage, the best time to check on equipment and related systems to make the right decisions that will help to enhance the performance of the total system and reduce on system downtimes as much as possible. This orientation for data supports the transition from the more conventional corrective to preventive maintenance methods, which positively impacts organizational performance and availability.

### D. Hierarchical Models for Root Cause Analysis

Hierarchical models, as they have been established, are effective tools for root cause analysis when dealing with intricate production systems. These models divide problems into easier-to-solve pieces when they categorize issues at one or the other levels like the machine level, process level or system level. When it comes to issues of production downtime, hierarchical models are useful in providing a framework for analysis of the causes of production downtime. Such models grouped into a multiple hierarchy structure can help distinguish whether certain problems result from a mechanical failure or operator mistake, a lack of effective procedure, or other causes. This approach enables enhanced intervention by simultaneously identifying restricted causes.

## III. METHODOLOGY

### A. Overview of the Proposed Framework

The proposed methodology, therefore, involves a database-oriented optimization [13-17] strategy incorporating hierarchical models. Figure 1 presents the overall framework, which consists of four main phases:

#### a) *Data collection and data cleansing:*

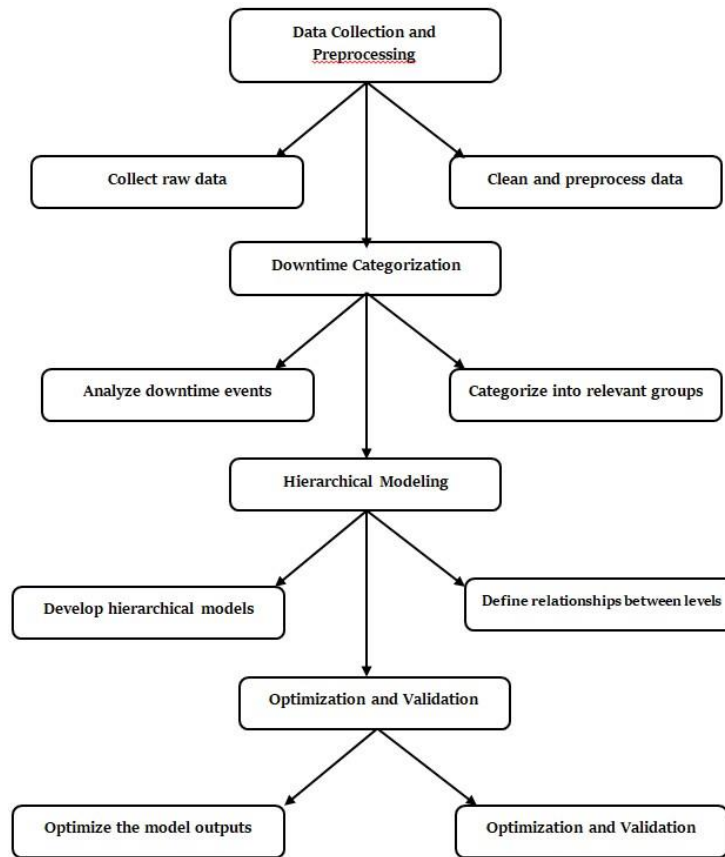
In the first phase, a lot of important data is gathered and sourced from several areas, such as sensors, records of the past, and logs of activities being done. Such raw data is then cleaned to make it of adequate quality and to be listed under the required format. The preprocessing process involves a transformed process involving data cleaning, missing values, and normalizing the data to prepare the data for further analysis. This specific phase sets the groundwork for avoiding ineffective and inaccurate models.

b) *Downtime Categorization:*

The second phase classifies downtime events by dividing them into meaningful classes from the collected and preprocessed data. User downtime can be caused by equipment failure, prohibitive time spent on maintenance schedules or poor systems utilization. Downtime events are classified into one category while identifying the event's major causes. This categorization offers a better view of what can be seen as ‘downtime’ patterns, contributing to the formulation of solution strategies.

c) *Hierarchical Modeling:*

In the third phase, the hierarchical models are constructed to reflect the interconnection of distinct parts of the system and the amount of time that cannot be used. As such, these models are developed at multiple levels covering system and detailed levels such as equipment or process levels. Hierarchy aids in disaggregation and can thus be used effectively to work out causations and effects within a system.



**Figure 3: Overview of the Proposed Framework**

d) *Optimization and Validation:*

The last step is tuning the system according to the knowledge obtained from the used hierarchical models. The latest optimization techniques that may help reduce the amount of time that the system is not operational while maximizing performance are used. These summaries are then tested using simulation or real implementation to confirm their efficiency in the work. It also guarantees that the provided framework effectively produces tangible output that should answer questions of how best to increase the efficiency of operation.

**B. Data Collection and Preprocessing**

a) *Data Sources:*

Data used in this work originates from machine logs, sensor information, maintenance documentation, and production calendars. According to the sources, this information explains machine activity, downtime occurrences, and performance parameters necessary for analysis. Machine logs comprise actual information on the operating state of a machine, while the

sensor data provides the detailed status of the machine. The maintenance reports point at historical problems, while production schedules assist in linking the period of downtime with the production schedule.

*b) Data Cleaning:*

Raw data is usually unsuitable for analysis as it contains errors, migrations, missing values, or even twice the same record. Data cleaning is about screening outliers; missing values are taken care of by imputing methods and removing any repetitive data to ensure that the data collected is clean. Creating a solid, cleaner dataset that will facilitate analysis and provide leverage for actual and valuable conclusions in the later stages is essential.

*c) Feature Extraction:*

The next step is a structure to analyze critical characteristics relevant to downtime, including the length and number of downtime events, the kinds of machines, failure origins, and operational environments. These features are selected statistically and often with reference to expertise in the field to derive meaningful ones. The extracted features are used to input the hierarchical models that provide an explicit approach to the understanding of downtime factors as well as their interdependency.

### C. Downtime Categorization

*a) Machine Failures:*

Machine downtimes pertain to stoppages due to mechanical or electrical problems that affect the normal running of the machine. These failures are normally critical and measured to cause the biggest part of any downtime event and contribute to about 40 % of overall downtime. The frequency and causes of machine failures must be known to ensure that maintenance approaches are applied effectively to increase equipment reliability.

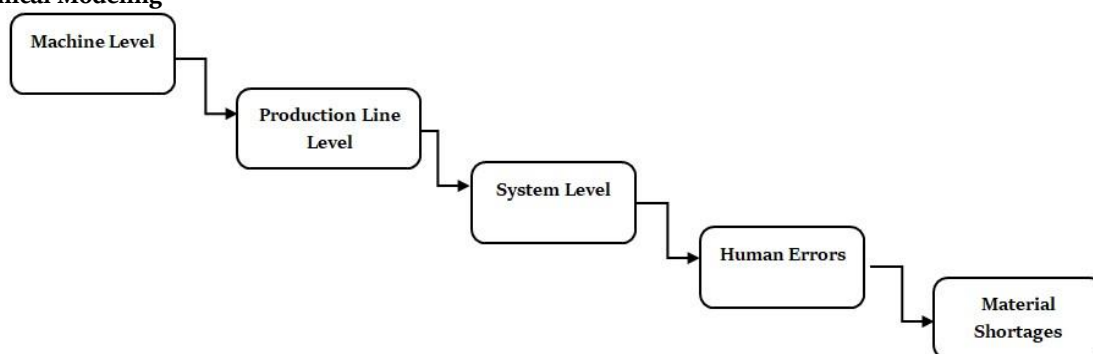
*b) Scheduled Maintenance:*

Planned maintenance consists of activities targeted towards preventing a failure from occurring and improving the performance of equipment in use. Inspections, change of parts, or other usual operations, which are carried out in comparison with failure effects according to the schedule, constitute 25 % of overall standstill time. Even if the proper long-term throughput costs are considerably more than standard productive costs due to increased risks, optimizing the frequency and duration of scheduled maintenance may help control the negative effects of the process on production.

*c) Unscheduled Maintenance:*

Unscheduled maintenance consists of maintenance performed unscheduled because minor faults occur, which cannot wait for any scheduled maintenance. Despite being typically less dramatic in comparison to critical failures, these occurrences are random and can cause disruptions that introduce delay. Unplanned maintenance accounts for 15 percent of downtime and therefore support fault detection and response as soon as possible.

### D. Hierarchical Modeling



**Figure 4: Hierarchical Modeling**

*a) Machine Level:*

At the machine level, analysis of machine failures uses a decision tree to establish the possible causes of machine breakdown at different decision-making levels. These analytical models define how key machine parameters, which include temperature, vibration, and operation time, are associated with failure events. Through the understanding of the said relations, the models help identify failures at an early stage and necessary corrective measures formulated to minimize the duration and improve the dependability of the machines.

*b) Production Line Level:*

The production line level sum of data generated from the machine level analyses to grasp the macro picture across connected singular machines in the production robustness. Thus, when determining machine dependencies and analyzing critical sections of production lines, it is possible to develop models for maintenance schedules at the level of individual production lines. This approach also ensures that maintenance interventions are properly scheduled to avoid much interruption of production processes, thereby improving productivity.

*c) System Level:*

At the system level, a complete review of the unavailability is done using sophisticated time series forecasting approaches. These models use past trends and downtime occurrences to improve the foreseeable future and downtime events to provide optimum decision-making. System-level models enable optimum organizational comparisons, workforce assignments, and strategic maintenance timing through implemented downtime, thereby enhancing system performance and minimizing expense risks in its useful life.

*d) Human Errors:*

Operator error happens when the operator gets it wrong during production or maintenance, causing interference or loss of productivity. These errors, which make up 10% of total downtime, can entail wrong manipulation of tools and equipment, slowness in carrying out functions or Drawing a wrong conclusion when diagnosing a problem. It is, therefore, important to deal with human errors through training and organizational change, which include fixing the process.

*e) Material Shortages:*

Occasionally, there's a material shortage, which means that the raw materials or some crucial input is missing, leading to production stops. These delays contribute to 10% of total production shutdown time and are associated mostly with irregularities in the supply chain or poor or improper management of stocks. These delays can be minimized by strengthening the ways of purchasing materials and keeping enough stock to avoid production disruption.

## **E. Optimization and Validation**

Genetic algorithms and scheduling heuristics are used to avoid more hours of facility downtime by analyzing the best possible way to conduct maintenance. [18-20] These algorithms incorporate approaches at the machine level, at the production line level, and at the system level to determine the right time to carry out maintenance activities and in the most efficient methods so that they do not interrupt production. The optimization process thus leads to an increase in system availability, maximising resource utilisation, hence improving efficiency. The applicability of the proposed framework is then checked by back-calculating the obtained downtime values from historical downtime data and applying it to real-life examples. This guarantees that the improvements needed in the framework are achieved not only in theoretical terms but also in practice, where systems are in operation.

## **F. Proposed Downtime Optimization Framework**

A rational plan for fixing the downtime problems. They include identifying the downtime issue and identifying the root of known downtime. If the cause is known, then we proceed to categorize the cause and see if it can be dealt with internally. When it is solvable internally, people insist on a solution, and a team is developed to address the issue and later check if it was solved. If within the organization, it is still not possible to solve the problem, outside help is sought, and constant checks are made to ensure that the issue is solved at that particular place. In some cases where the reason behind the defined downtime period is not clear, a root cause analysis is done, and the cause database is updated. The same is true for the cause identified and categorized: one must decide whether it will be solved internally or externally and then check the result. After that, an attempt is made to resolve it, and then the program evaluates the degree of its full enrollment. If so, then the possibility of recurrence is prevented by bringing changes in the measures recorded and the solution written. In case the problem persists, it becomes escalated, and an improved resolution is created. Some of the steps that are done in the last are logging the downtime and resolution data, assessing the process for proper optimization points and implementing the lessons in order to enhance the mitigation approach. This lends a systematic basis to the method of approaching, diagnosing, documenting, and managing solutions relating to downtime problems. The flowchart shown above is a step-by-step approach to eliminating, investigating and solving downtime problems. It starts with a downtime problem, which splits into two scenarios depending on the presence of known downtime cause. If the reason for the downtime is identified, then the next step is indexing. If not, the root cause is determined to find the problem's real source and the cause database is modified to contain records of such causes. The second process establishes if the cause must be dealt with or if it needs the assistance of outside help.

Problems can be internally solved, and a workgroup is given the task to affect a solution. The solution known to have been implemented is then checked to affirm that the problem is fixed. When issues cannot be resolved within the organization, external assistance is called in, and the progress of the resolutions is observed. In both cases, the process identifies whether it has been solved positively or not. Here, the agreement is that if the problem is solved, then documentation of the solution happens. Mitigating factors are modified to prevent such downtime in the future so that other preventative measures can be taken. Subsequently, the time of the message posting is logged along with the downtime and the resolution data. After this, a paper on the optimization of mitigation measures is produced, and the information is incorporated to enhance subsequent reviews. This is important in order to avoid making the same mistakes over and over again when developing future responses. In the case where the problem is not handled during verification, further review is then preceded. A more enhanced resolution plan is formulated and actioned, and the process returns to verification. This means that issues not settled here will be discussed with further attention, and more efforts will be made to find a solution.

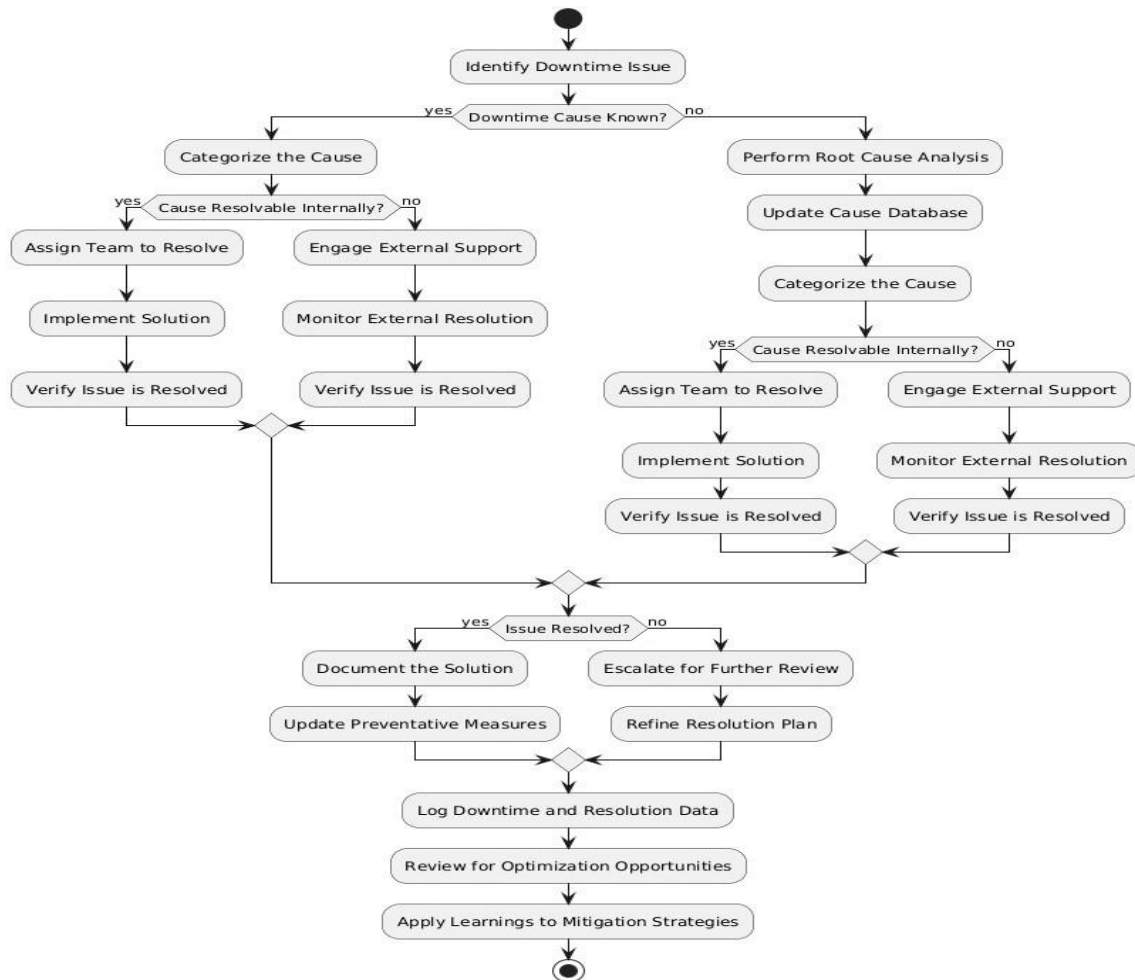


Figure 5: Proposed Downtime Optimization Framework

#### IV. RESULTS AND DISCUSSION

##### A. Downtime Analysis Results

Thus, using the hierarchical model enabled straightforward categorization of downtimes and increased system efficiency. Key results are as follows:

##### a) Unplanned Downtime: Reduced by 15%:

The saving of 15% in unplanned downtime is also impressive, which means the system’s reliability has increased over time. By use of a hierarchy model to pinpoint and solve likely causes of interrupted workflow, differential preventive maintenance and detailed planning were adopted. It eliminated disruptions of workflow, hence enhancing flows, reducing operation costs, and providing a better return on investment. The model's capability to identify risks and prevent them from



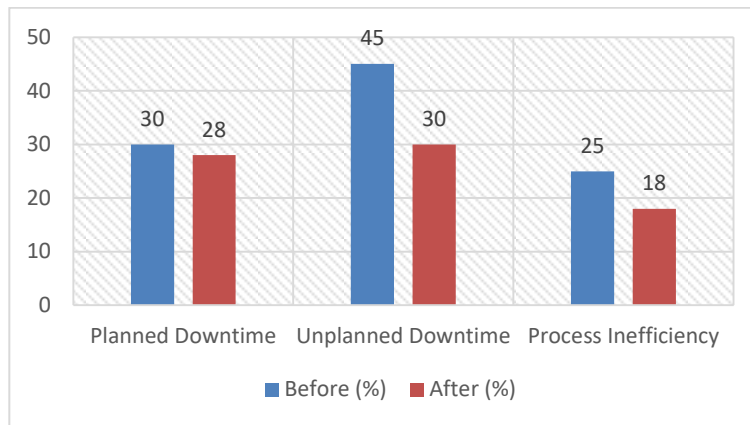
developing into severe threats before they occur was a key factor in the entrenchment of a reduction in unplanned downtime, thereby establishing a more durable system.

*b) OEE Improvement: Increased by 10%:*

A rise in OEE by 10% means dramatically improving equipment usage productivity within a process. OEE is one of the important performance indicators that incorporate the actual availability of the machine, its performance, and quality. By adopting the hierarchical model of recognizing lonely points on the Shop Floor, various business constraints surfaced, which led to creating an efficient schedule to increase machine availability and utilization based on capacity. The increase in throughput results from the optimal use of resources, minimal scrap and higher levels of quality. Hence, the 10% OEE improvement proves that measured changes will enhance the operation and create more profits.

**Table 1: Downtime Reduction Comparison**

Downtime Type	Before (%)	After (%)
Planned Downtime	30	28
Unplanned Downtime	45	30
Process Inefficiency	25	18



**Figure 6: Downtime Reduction Comparison**

*c) Planned Downtime:*

They are based on organizational plans for shutdowns of operations for purposes such as maintenance, replacement, or equipment overhauls. These downtimes are required to restore the health of machinery, systems or processes and also to maximize efficiency in the long run. Thus, in the provided data, the average planned downtime is down to 28 percent, which could speak about either better planning or the lower need for scheduled operations. This decrease may be due to good scheduling and the application of new maintenance approaches, such as predictive maintenance.

*d) Unplanned Downtime:*

Planned downtime is deliberately scheduled as it happens when completing upgrades, maintenance or other changes to the current system. It interferes with operations and can considerably affect efficiency and expense. In the data collected, they have successfully managed to bring down the level of unplanned downtime from 45% to 30%, indicating improvement in the area of practices relating to maintenance, equipment reliability or troubleshooting. This decline results from internal and external preventive measures, improved early warning systems, swift mitigation measures, and effective protective maintenance measures against failure.

*e) Process Inefficiency:*

It measures output reducibility due to inefficiency in organization processes, delays, ineffective systems, etc. They include delays like anticipation, excessive production of inventories, and over-ordering of materials, which all drain time, manpower, and resources. The achievement of moving from 25% to 18% on the data supports improvements in operations processing. This improvement could be made due to proper organization, enhanced knowledge of the employees, mechanical means or adoption of lean management to reduce sequence waste.

**B. Model Performance**

The performance of the hierarchical model was evaluated using accuracy and precision metrics for different modeling techniques:

*a) Regression Accuracy:*

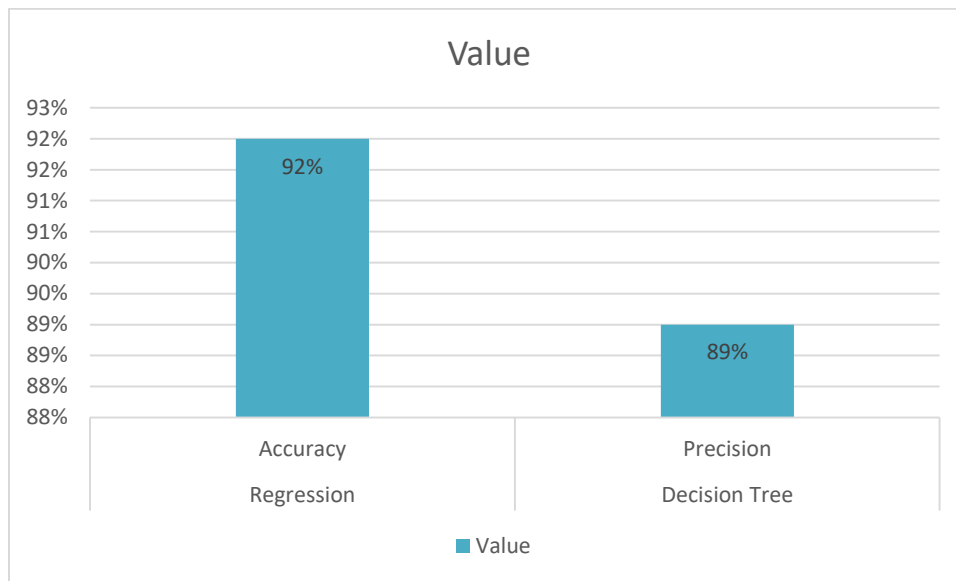
The regression model also used a very high accuracy of 92 %, indicating that the forecasts were accurate based on historical data. Such a level of accuracy proved that the developed model is very useful in identifying the system behaviors and performance in terms of downtime or productivity. Matters of relative quantities and proportions were adequately followed by the complex analysis of the relationships between the variables, and that made for correct predictive patterns. The fact that the model achieves 92% accuracy means that the model can be relied on to make proper decisions that would be of great help in enhancing system performance and reducing the system’s inefficiencies.

*b) Decision Tree Precision:*

The precision rate of the decision tree model was 89%, as the outcome showed while using this technique. It can efficiently identify the various causes of downtime or performance failure, and the classification of the related results is also accurate. Precision evaluates the frequency of true positives compared to all possible positives, which means that the decision tree merely selected relevant inputs without going wrong very often. Such a precision rate indicates that the factors influencing decision-making are determined accurately, and ways to correct them are instituted efficiently to make the system tighter, thus increasing efficiency.

**Table 2: Model Performance**

Modeling Technique	Metric	Value
Regression	Accuracy	92%
Decision Tree	Precision	89%



**Figure 7: Model Performance**

**V. CONCLUSION**

This work was able to show that condition monitoring based on a database with hierarchical models can significantly improve the timeliness of production in the pharmaceutical industry. By addressing the reasons associated with the degree of downtime, the method allowed to minimize the degree of unpredictable downtimes by 15%, which contributed to the improvement of the total outcome of the production process. Instead, reducing the rates of unexpected stoppages not only prevented operational interruptions but also reduced the costs and wastage of various resources, hence establishing more reliable running processes. In addition, the study also revealed that OEE, a key factory productivity measurement that compares equipment availability, speed and product quality, improved by 10 per cent. This increase in OEE helped to show greater productivity from equipment, as well as less overall waste and defective products, giving greater profitability. The deployment of

the hierarchical model that was used in the study also highlighted areas of wastage, constraints and potential sources of breakdowns, which were subsequently addressed, leading to an improvement in the flow of production. Besides the enhancements on the downtime and OEE, the study also incorporated a machine learning model, which gave a predictive maintenance function. Because of this proactive maintenance management tactic that was adopted, failures in equipment were noticed beforehand, thus preventing the interruption of work caused by equipment failures. Through the use of data-derived decisions, the manufacturing process was able to detect possible problem areas and deal with them before they became a problem in the manufacturing line. They brought improvements to the production process to make it more dependable, efficient and not very expensive.

Future work will be more directed at integrating the Internet of Things sensors in the system in order to acquire data in real-time. Connection of further IoT sensors is shown to perform ongoing monitoring of the equipment, ambient and working conditions, and parameters, which would offer a rich source of additional timely data for further enhancement. This data would enable much more accurate forecasting and analyses of the manufacturing process and prompt reactions to emerging problems. While continued implementation of traditional hierarchical models of supply chain management has its merits, such a system could be further improved if manufacturers adopted IoT: a more flexible, interactive and efficient solution. From a broader perspective, this study established a significant premise for the continuity of the enhancement of data analytical approaches to the pharmaceutical manufacturing organization with promising improvement in operation performance and cost saving.

## VI. REFERENCES

- [1] Khelifi, M. (1999, November). Downtime reduction with updated Maintenance system. In SPE/IADC Middle East Drilling Technology Conference and Exhibition (pp. SPE-57559). SPE.
- [2] Tabikh, M. (2014). Downtime cost and Reduction analysis: Survey results.
- [3] Vegunta, S. C., & Milanovic, J. V. (2009). Estimation of cost of downtime of industrial process due to voltage sags. *IEEE Transactions on power Delivery*, 26(2), 576-587.
- [4] Patti, A. L., & Watson, K. J. (2010). Downtime variability: the impact of duration–frequency on the performance of serial production systems. *International Journal of Production Research*, 48(19), 5831-5841.
- [5] Jeong, K. Y., & Allan, D. (2004, April). Integrated system design, analysis and database-driven simulation model generation. In 37th Annual Simulation Symposium, 2004. Proceedings. (pp. 80-85). IEEE.
- [6] Biswas, G., & Mahadevan, S. (2007, March). A hierarchical model-based approach to systems health management. In 2007 IEEE Aerospace Conference (pp. 1-14). IEEE.
- [7] Matsukawa, T., Funakoshi, H., & Koshiji, K. (2011, January). Evaluating downtime and maintenance time in communication networks. In 2011 Proceedings-Annual Reliability and Maintainability Symposium (pp. 1-6). IEEE.
- [8] Ganesh, S., Su, Q., Pepka, N., Rentz, B., Vann, L., Yazdanpanah, N., ... & Reklaitis, G. V. (2020). Design of condition-based maintenance framework for process operations management in pharmaceutical continuous manufacturing. *International journal of pharmaceutics*, 587, 119621.
- [9] Anand, G., Gray, J., & Siemsen, E. (2012). Decay, shock, and renewal: Operational routines and process entropy in the pharmaceutical industry. *Organization Science*, 23(6), 1700-1716.
- [10] Islam, M. Z., Mamun, Q., & Rahman, M. G. (2014). Data cleansing during data collection from wireless sensor networks. In Proceedings of the twelfth Australasian data mining conference (AusDM 2014) (Vol. 11).
- [11] Enyinda, C. I. (2009). Modeling risk management in the pharmaceutical industry global supply chain logistics using analytic hierarchy process model. North Dakota State University.
- [12] Stonier, A., Smith, M., Hutchinson, N., & Farid, S. S. (2009). Dynamic simulation framework for design of lean biopharmaceutical manufacturing operations. In *Computer Aided Chemical Engineering* (Vol. 26, pp. 1069-1073). Elsevier.
- [13] Bevilacqua, M., Ciarapica, F. E., De Sanctis, I., Mazzuto, G., & Paciarotti, C. (2015). A Changeover Time Reduction through an integration of lean practices: a case study from pharmaceutical sector. *Assembly Automation*, 35(1), 22-34.
- [14] Srari, J. S., Kumar, M., Graham, G., Phillips, W., Tooze, J., Ford, S., ... & Tiwari, A. (2016). Distributed manufacturing: scope, challenges and opportunities. *International Journal of Production Research*, 54(23), 6917-6935.
- [15] McWilliams, J. C., Allian, A. D., Opalka, S. M., May, S. A., Journet, M., & Braden, T. M. (2018). The evolving state of continuous processing in pharmaceutical API manufacturing: a survey of pharmaceutical companies and contract manufacturing organizations. *Organic Process Research & Development*, 22(9), 1143-1166.
- [16] Burcham, C. L., Florence, A. J., & Johnson, M. D. (2018). Continuous manufacturing in pharmaceutical process development and manufacturing. *Annual review of chemical and biomolecular engineering*, 9(1), 253-281.
- [17] Steiner, R., & Jornitz, M. (2017). Continuous processing in the pharmaceutical industry: status and perspective. *Continuous Manufacturing of Pharmaceuticals*, 369-403.
- [18] Chikwendu, O. C., Chima, A. S., & Edith, M. C. (2020). The optimization of overall equipment effectiveness factors in a pharmaceutical company. *Heliyon*, 6(4).

- [19] Vargas, J. M., Nielsen, S., Cárdenas, V., Gonzalez, A., Aymat, E. Y., Almodovar, E., ... & Romañach, R. J. (2018). Process analytical technology in continuous manufacturing of a commercial pharmaceutical product. *International journal of pharmaceutics*, 538(1-2), 167-178.
- [20] Hattori, Y., & Otsuka, M. (2017). Modeling of feed-forward control using the partial least squares regression method in the tablet compression process. *International journal of pharmaceutics*, 524(1-2), 407-413.