

Analysing the Impact of Autonomous Maintenance on the Packaging Line of a Pharmaceutical Industry

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Abstract

To meet the market's challenges, industries are today confronted with a difficult situation, particularly maintaining product quality at competitive costs. Such a condition necessitates an increase in productivity with decreased expenses. Autonomous Maintenance (AM) facilitates this for industries. This project intends to integrate Autonomous Maintenance (AM) in a pharmaceutical manufacturing line, with a focus on the needs of a developing-country business. The focus of the research has been on operator training as the primary component of autonomous maintenance. It tries to instill a sense of responsibility for machine maintenance among machine workers. This allows the maintenance staff to focus on other essential responsibilities. The analysis of recurring losses and their resolution established the basis for the implementation of AM. The required for Scheduled Maintenance was lowered by 2.61 hours per week. Since the deployment of AM, the OEE has been on the rise and is approaching the world-class level of 80%. AM has cut unscheduled downtime by more than 100 percent and prevented additional changeover delays. As a result of a 6% improvement in total uptime, typical shift times have been lowered, bringing significant benefits to both the firm and its personnel. The report proposes that stakeholders continuously seek chances for development and expand the scope of additive manufacturing by incorporating activities known to affect the production efficiency of manufacturing lines.

Keywords—Autonomous Maintenance, Changeover, OEE, Production efficiency, unplanned downtime; uptime

1 Introduction

INDUSTRIES currently work within an economic framework where there is a persistent hunt for cost-reduction methods and increases in productivity with minimal investment to make. As consumer demand is ever-increasing, it is necessary for industries to advance and adopt new production technologies and techniques, as well as management procedures that provide no chance for failure or waste. Industries work in a competitive environment, necessitating continuous enhancement of activities, including reforming the maintenance framework [1] by engineers in a way that maintenance does not interfere with the course of production. To achieve this, maintenance techniques must be drawn up in such a way that possible breakdowns of equipment are reduced to a minimum. Companies have learned that if maintenance

is ignored, the equipment will make them pay for it. To optimize the maintenance system, companies have turned to Autonomous Maintenance, a tool that enables organizations to meet their objectives of zero breakdowns, zero defects, and zero accidents [2]. The idea behind autonomous maintenance is to provide the operators with more accountability and enable them to carry out preventive maintenance tasks, reducing technicians' involvement, planned maintenance needs, and hence related time loss [3]. AM is derived from a Japanese maintenance management system that allows operators to run minor maintenance work sparing skilled maintenance staff for challenging tasks: Jishu Hozen (JH) [4]. In Pakistan, large Pharmaceutical industries face productivity challenges as many local drug companies rise in the market to compete, so the industry needs to maintain the required quality standards of their product and to keep it free of the defect [5]. Autonomous maintenance ensures maximum use of plant equipment to increase production without affecting quality helping largely the industry

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achieve its goals [2]. The plant where this study is done has already implemented two pillars of total productive maintenance strategy, i.e., safety, health, and environment, and focused improvement/Kaizen. The study advances TPM implementation by employing the autonomous maintenance program along with the necessary functions of training and education. AM studies are required so that investments can reap maximum benefits in Pakistan, enabling industries to contribute more favorably towards the economy of the country [6]. This study also aims to analyze hindrances to autonomous maintenance and address those issues to make it a viable tool for developing countries, especially for their small and medium enterprises (SMEs) that form a major chunk of industries in those countries.

2 Objectives

The following are the objectives of the study:

- 1) To identify possible losses incurred and factors contributing to those losses.
- 2) To develop an autonomous maintenance system for a pharmaceutical packaging line.
- 3) To analyze and monitor the impact of AM on key productivity indicators.

3 Literature Review

Many industries strive to bring innovative ideas to stay relevant in a competitive business scenario. As a result, there has been a constant search for methods to improve production processes and organizational functions. Lean maintenance strategies were employed in the pharmaceutical industry to reduce the waste in maintenance services [7]. Autonomous Maintenance (AM) allowed industries to reduce the changeover time and maintenance workers' work hours [8]. For operators, AM maintenance evolved from helping fix defects to doing system maintenance and taking up routine machine upkeep tasks. Operators also manage troubleshooting and problems at the line. A study gathered information about vital success factors for pharmaceutical firms from lower-, middle-, and top-level managers. Here, Autonomous Maintenance was identified as a critical success factor for competitiveness and savings [9]. Total Quality Management (TQM) has allowed a paradigm shift in Pakistani process industries [10]. TQM has been adopted to reduce losses and increase the utilization of machines. By coupling TPM and TQM various positive effects have been observed in mechanical downtime, waste reduction, and employee awareness [10]. There has been an acknowledgment that continuous improvement of

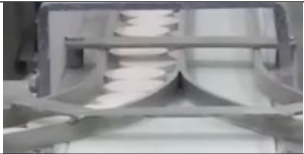



workers' knowledge and enhancement of their skill set at different levels, a vital component of AM, is vital for continuous improvement in the industry [11]. Autonomous Maintenance was identified as a critical success factor for competitiveness and cost savings in a study including top and middle-level managers [9]. Further, it has been noted that AM prevents the deterioration of equipment. It builds and promotes a culture of accountability, safety, and quality [6]. The implementation of autonomous maintenance had a positive impact on workers and enhanced the work environment at the plant. This increased job satisfaction of employees on the floor was found to be vital for the success of the firm [12]. OEE is recognized as the established benchmark for performance evaluation of the implementation of various improvement techniques including Autonomous Maintenance (AM) [13].

4 Methodology

This quantitative research is at a drug manufacturing plant in Sindh, Pakistan. The plant has about 300 employees. The products of the plant are available in the local market as well as for export. For this study production and maintenance processes and routines were studied. The research aim and methods were conveyed to the stakeholders in meetings for this study. The first stage of the study included studying the recurring losses that caused frequent delays on the production line, the Pareto Analysis [14] and Root Cause Analysis were done to establish improvements needed and design of regular maintenance program. In the next step, the critical tasks that were to be done daily, weekly, or fortnightly were recognized and adopted. Root Cause Analysis (RCA) is employed here as it is widely used in IT operations, manufacturing, telecommunications, industrial process control, accident analysis, and other applications [15]. Pareto Analysis gives efficient results and helps management in the resolution of the most vital hindrances to production [14]. Finally, the OEE, breakdown, and other times' data were collected for analysis. The implementation of AM entailed the identification of issues within the current system of maintenance and losses encountered. Table 1 shows problems encountered frequently in line with their major impacts.

5-Why Analysis and Fishbone diagram techniques helped resolution of these problems and specify the corrective actions. One key Corrective action and Preventive action was the inclusion of parameters and adjustments causing top issues in AM program. This formed the basis of AM program. The next step of the study was designing and implementing the Autonomous Maintenance tool that enhances machine

TABLE 1: QUANTIFICATION OF MAJOR LOSSES WITH THEIR EFFECTS

Sr#	Problem	Major Effects	Total Breakdown Time hrs/month	Picture
1	Tablet sticking problem	Broken Tablets; Rejection clearance delay; edges cut-off	8.2	
2	Pressing device issue	Powder on tablets; foil not wrapped properly	8.6	
3	Aluminum foil missing at Theegarten machine	Tablets wrapping problem; Aluminum foil wastage; manual foil change	12.7	
4	Sohnel machine Alarm error	Tube missing; cap and tube stuck	11.5	

productivity and effectiveness. The implementation was based on the Japanese technology of Jishu Hozen (JH) [15] and the scheme applied was CILT (Cleaning, Inspection, Lubrication, and Tightening) technique. Table 2 lists the stages of AM process as adopted in this study.

Table 3 shows some actual specific steps of Autonomous Maintenance (AM) that were included in AM sheet for operators to give insight into the implemented AM program. To quantify the benefits of Autonomous Maintenance implementation before and after the implementation date was gathered fortnightly for analysis. Analysis was done by comparing the OEE which was known from OEE sheets maintained by operators and also online system software. The software also gave insights about losses, minor stops, and breakdowns at the line. Data about preventive maintenance was extracted from the Engineering calls to register and Computerized Maintenance Management System (CMMS). Analysis of results was done using SPSS software. Paired samples t-test was employed to find the significant parameters where AM impacted. P-value was used to check the significance of the outcome.

5 Results

Analysis of data was done to analyze the impacts and benefits of AM on the productivity of the packaging line. The most evident impact was on the OEE of the line which showed an overall increasing trend after

the implementation of AM and approaching the world-class benchmark of 80% (Figure 1).

Unplanned downtimes (UPDT) that were the cause of frequent delays on the production line were reduced significantly due to AM program from a mean value of 31.2 to 14.0 as shown in Table 4. It can also be noted in Table 4 that unplanned downtime as a percentage of actual shift time has reduced; this is statistically supported by a strong t-value of 6.208 and a significant p-value ≤ 0.005 . Table 4 shows that change over time along with total preventive time reduced significantly from a mean value of 29.8 to 19.5 and 8.31 to 5.7 hours respectively. All these time savings also resulted in a gradual reduction of total shift time where the mean is reduced by 32.6 hours. t-values and P-values show a significant reduction in mean as a percentage of scheduled time in total preventive maintenance, UPDT, and changeover times.

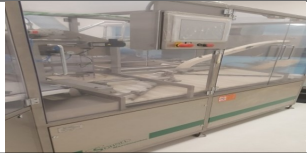
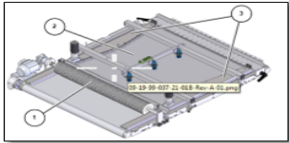
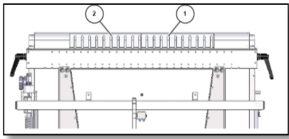
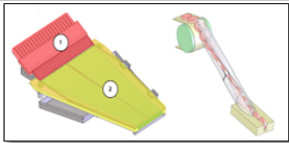
Table 5 shows that uptime as a percentage of scheduled time increased significantly to 71.3% ($p - value < 0.005$). Table 5 further shows a significant reduction in total preventive maintenance time, unplanned downtime, and excess changeover times. All values were significant to ($P - value < 0.005$) level.

To verify the impact of AM on planned maintenance (PM) times, Pearson correlation was applied between unplanned downtime and planned maintenance. It can be seen in Table 6 that there is no significant relationship between both.

TABLE 2: DESCRIPTION OF STAGES IN THE IMPLEMENTATION OF AUTONOMOUS MAINTENANCE

Stage	Description
0	This is the preparation step. Before initiating the process awareness regarding the issue of deterioration and equipment’s useful life was imparted. Employees were given an understanding of the problems associated with forced deterioration.
1	In this step, operators were made to understand the probable hazards and safety precautions, initial cleaning & inspection concepts, abnormalities identification, and classification of abnormalities along with their occurrence and removal of those abnormalities.
2	This step involves the elimination of dirt sources and difficult-to-access areas. A source of contamination map was prepared and countermeasures to remove difficult-to-access areas were established and action taken.
3	In this stage cleaning and inspection protocols were standardized. Steps 1 and 2 allowed for practitioners and operators to clarify the ideal conditions and what needed to be done in what way so those were used to establish steps. 5S philosophy was put to use here.
4	This step made operators understand the equipment structure, functions, principles, and optimal conditions. Operators acquired the skills needed to check the parts that needed to be maintained for smooth functioning. Here general inspection standards were developed.
5	To sustain the viability of general inspection overall inspection protocols were set. To maintain the reliability of the process, visual management techniques were set to facilitate the operators and maintenance technicians in detecting machine problems.
6	This study included maximizing the capacity of operators and providing them with autonomy. Here, along with the daily maintenance with standardized check sheets, the operators were given the role to inspect the conditions and equipment surroundings to drive down the losses to a minimum. Analysis of equipment requirements allowed operators to manage their work. A mechanism was also set for operators to report any abnormality as well as present ideas for production improvement.
7	As improvements are a continuous process and result of synergic effort, maintenance staff and operators were grouped as a team to look after the machines. Training of operators and the relevant staff was carried out in this stage to efficiently harness AM benefits.

TABLE 3: CILT SHEET ELABORATING SPECIFIC STEPS FOR OPERATORS

Device Work Instruction	Part Diagram	Work Execution Procedural Steps
Lockout & Tag-out Machine Powers		Follow LOTO procedures displayed on the Machine
Filling machine (general)		The machine must be cleaned every week according to the information given below. Make sure that you use only cleaning agents with no alcohol or chlorine. No moisture must penetrate electrical components or housings. All transparent protection doors and covers can be cleaned with a towel. The machine must be thoroughly dried after cleaning.
Tablet in-feed conveyor		1. Clean and inspect for the condition of The tablet turning brush (1) in front of the sensors rotating against the tablet flow to separate tablets lying on top of other tablets. 2. Thoroughly inspect the condition and gently clean the pet-down device mounted below the sensors (2) 3. Thoroughly inspect the condition and clean the vertical side belts which are mounted above the tablet in-feed conveyor. 4. Gently clean all sensors.
Tablet channels		1. Thoroughly inspect the condition and clean all guiding elements. 2. Thoroughly inspect the condition and clean all connection elements which distribute the tablets on all tracks so that each tablet turning device is filled with tablets.
Tablet turning device and tablet tracks		1. Thoroughly inspect the condition and clean all tablet turning devices (1) 2. Thoroughly inspect the condition and clean all tablet tracks (2). 3. The entire unit can be cleaned with a vacuum cleaner when it’s installed, for this use a soft nozzle that reaches all grooves.

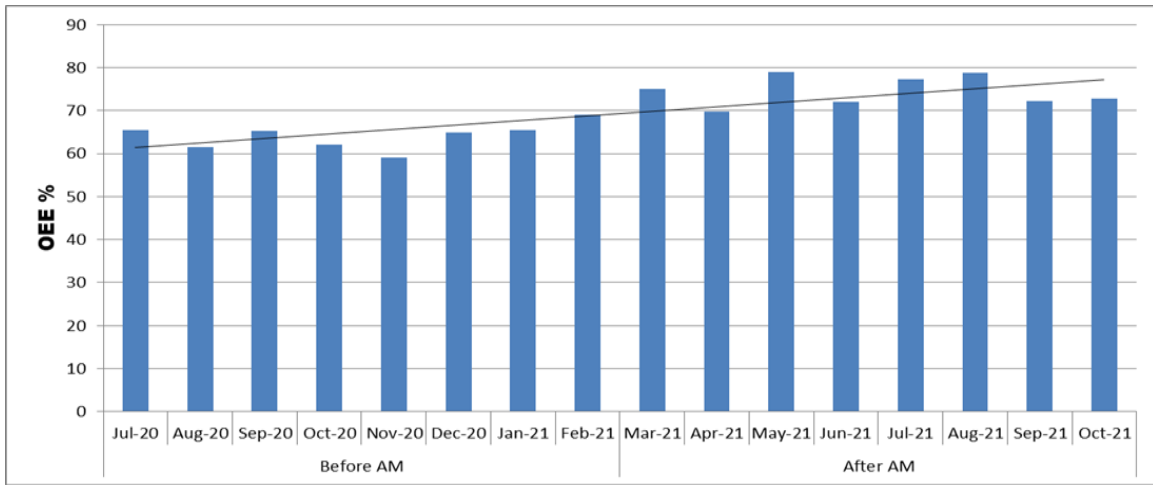


Fig. 1: OEE results before and after the implementation of autonomous maintenance

TABLE 4: TIME CONSUMED IN DIFFERENT ACTIVITIES BEFORE AND AFTER AUTONOMOUS MAINTENANCE IMPLEMENTATION

	Before AM implementation		After AM implementation	
	Maximum	Mean value	Maximum	Mean value
Total Shift time/hrs.	314.0	237.8	280.0	205.2
Total Preventive maintenance/hrs.	11.0	8.31	7.0	5.7
Unplanned Downtime/hrs.	55.0	31.2	21	14.0
Changeover time/hrs.	41.0	29.8	30.0	19.5

TABLE 5: VITAL PARAMETERS AS A PERCENTAGE OF SCHEDULED TIME

	Before AM implementation		After AM implementation	
	Mean (%)	S.D.	Mean (%)	S.D.
Total Uptime	64.9	3.6	71.3	3.3
t(15)	5.067			
p-Value	<0.0005			
Total Preventive maintenance	3.6	0.9	2.8	0.4
t(15)	-3.260			
p-Value	0.005			
Unplanned Downtime	13.0	3.8	6.8	0.8
t(15)	-6.208			
p-Value	<0.0005			
Changeover time	12.5	2.3	9.6	1.2
t(15)	-3.663			
p-Value	<0.005			

TABLE 6: RELATIONSHIP OF PM DOWNTIME AND UPDT AS A PERCENTAGE OF THE SCHEDULED TIME

PM downtime as %age of scheduled time	Unplanned downtime as %age of scheduled time	
	R-Value	-0.061
p-value	0.810	

6 Discussion

The key objectives of the research were to implement Autonomous Maintenance on the packaging line to derive the benefits and analyze the impact on productivity indicators as suggested in other studies. The results of the present study showed that there was a visible improvement in the OEE of the line that is in line with other studies [15], [16]. OEE improvement has been on a shaky trend in developing countries due to several factors hindering the regular achievement of world-class OEE benchmarks [17], [24]. In this study successful training of operators helped significantly in the reduction of downtime at the line, this was shown in other such studies conducted [18]. Careful planning and designation of required parts along with operators' understanding of various processes helped eliminate several unproductive times such as lengthy and repetitive preventive maintenance schedules and changeover times, as reported in several other studies conducted for manufacturing organizations [4], [19], [20]. Actual productive time which was reported as actual uptime was analyzed and optimized in various studies of autonomous maintenance to make maximum use of available time and continue production [6], [21]. The issues encountered in the implementation of AM in this study were typical of most developing countries [17], [22], [23]. Results suggest that reduced downtime is not the reason that impacts the maintenance activities, but it is the regular upkeep due to the implementation of Autonomous Maintenance that resulted in the maintenance department reducing the maintenance work at the line after noting the reduced requirement. The study suggests that total shift time is reduced, which can translate for the industry in savings and early demand accomplishment and also an incentive for employees in producing additional goods over and above targets.

7 Conclusion

It was concluded from the study that Autonomous Maintenance (AM) is a viable tool for critical industries such as pharmaceuticals. AM implementation can reap positive benefits for critical industries in developing countries if implemented accordingly. AM helps meet targets in less time aiding in the reduction of shift hours for workers or added incentive of increased production capability. Some Suggestions and recommendations offered in light of the results and conclusion of this research work are:

- 1) Operator training should be focused on when implementing the AM in industries of developing countries.
- 2) Machine operators and maintenance personnel should continuously work to empirically determine the tasks that can be incorporated into AM plan and gradually reduce the formal maintenance requirements of the machine in a way that does not impact machine life.
- 3) Safety (HSE) requirements should also be a part of AM implementation for wholesome benefits to the industry, future research in Autonomous maintenance should incorporate this.

Conflict of Interest

There has been no reported conflict of Interest.

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