International Journal of Academic and Applied Research (IJAAR)
ISSN: 2643-9603
Vol. 10 Issue 2 February - 2026, Pages: 32-47

Lean–OEE Integration for Productivity Improvement and GMP Compliance in a High-Mix Pharmaceutical Packaging System: A Case Study

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Abstract: *This study investigates productivity degradation in a high-mix pharmaceutical packaging system operating under Good Manufacturing Practice constraints. The objective is to develop and validate an integrated Lean–Overall Equipment Effectiveness framework capable of diagnosing systemic inefficiencies beyond traditional utilization metrics. A single-case study design was employed within a regulated pharmaceutical packaging department. Value Stream Mapping, defect analysis, workload assessment, and Overall Equipment Effectiveness decomposition were combined with simulation-based evaluation to quantify performance losses and test improvement scenarios. The results reveal that high equipment utilization did not correspond to high productivity. Quality losses were identified as the dominant contributor to performance degradation, followed by performance losses related to setup instability and workload imbalance. Waiting waste significantly increased lead time. Integrated improvement scenarios reduced total lead time by approximately 22%, increased yield from 0.628 to 0.803, and improved throughput by 63.6%. Sensitivity analysis confirmed that these gains remained robust under moderate parameter variation. The findings demonstrate that productivity in regulated high-mix systems is driven by the interaction of quality stability, process variability, and human workload rather than equipment availability alone. The study contributes a systemic Lean–Overall Equipment Effectiveness diagnostic framework that integrates operational efficiency with compliance considerations. The results highlight the importance of defect reduction, setup stabilization, and workload balancing for sustainable productivity improvement in pharmaceutical packaging environments.*

Keywords— Lean Manufacturing, Overall Equipment Effectiveness, High-Mix Production, Pharmaceutical Packaging, Productivity Improvement, GMP Compliance

1. INTRODUCTION

Pharmaceutical manufacturing operates within one of the most tightly regulated industrial environments, where productivity, quality, and compliance must coexist without compromise. Increasing market competition, pricing pressure, and product portfolio expansion have intensified operational complexity, particularly in high-mix, low-volume batch production systems. Such systems are characterized by frequent changeovers, demand variability, short production runs, and heterogeneous material specifications, all of which increase operational instability and coordination complexity [1][2]. In pharmaceutical contexts, these operational characteristics are further constrained by Good Manufacturing Practice (GMP) regulations, which impose stringent documentation, validation, and traceability requirements [3]. Consequently, managing variability while maintaining compliance has become a central managerial challenge.

The literature on high-mix production systems emphasizes that variability amplification, setup frequency, and process interdependence significantly affect flow efficiency and yield performance [2][4]. In regulated pharmaceutical packaging operations, variability management becomes particularly critical because minor deviations can propagate across downstream processes, affecting defect rates and throughput stability. Empirical studies indicate that material variability—such as changes in blister packaging thickness or sealing properties—can alter process parameters and increase reject rates [5][6]. These operational challenges underscore the need for robust performance measurement systems capable of capturing not only output levels but also hidden inefficiencies embedded within the production process.

A recurring managerial problem in batch-based pharmaceutical systems concerns the gap between planned production targets and actual realized output. Production planning is often derived from nominal machine capacities and standard cycle times; however, actual throughput frequently falls short despite high machine utilization levels. This discrepancy raises questions regarding the relationship between capacity utilization and true productivity in regulated manufacturing environments. Several scholars argue that utilization metrics alone do not fully reflect system performance because they overlook quality losses, micro-stoppages, and performance variability [7],[8]. In complex systems, high utilization may coexist with low effective capacity when quality-related losses dominate. Therefore, reliance on traditional utilization indicators may obscure systemic productivity issues.

In addition to performance measurement limitations, production pressure and workload intensification may exacerbate compliance risks. When output targets are not achieved, organizations often respond by extending shifts or increasing operator workload. Research in human factors and quality management suggests that excessive workload and time pressure can elevate error probability and procedural deviations [9][10]. In GMP-regulated environments, such deviations carry significant regulatory consequences. Thus, productivity shortfalls are not merely operational inefficiencies but may also increase compliance vulnerability. Understanding the systemic interaction between productivity gaps, workload pressure, and regulatory risk is therefore critical.

General solutions proposed in operations management research emphasize the integration of structured performance diagnostics capable of decomposing losses into actionable categories. Lean Manufacturing provides a systematic framework for identifying non-value-adding activities, including waiting, defects, overprocessing, and imbalance [11][5]. Tools such as Value Stream Mapping (VSM) enable visualization of process flows and identification of bottlenecks or waste sources [12]. In parallel, Overall Equipment Effectiveness (OEE) offers a quantitative framework to evaluate equipment-related performance losses by decomposing them into Availability, Performance, and Quality components [7]. OEE has been widely applied in manufacturing environments to identify dominant loss categories and prioritize improvement initiatives [8].

More recent empirical studies advocate integrating Lean and OEE to achieve deeper diagnostic insights. Lean tools identify qualitative waste patterns, while OEE quantifies their impact on measurable performance outcomes [13]. In high-mix environments, where frequent setup adjustments and quality defects often outweigh breakdown-related losses, such integration becomes particularly relevant. Furthermore, research suggests that Total Productive Maintenance (TPM), when combined with Lean practices, strengthens process stability and reduces quality-related losses [14]. Importantly, in regulated industries, improvement initiatives must remain aligned with GMP principles to ensure that productivity gains do not compromise documentation and validation standards [3].

Despite these advances, a notable research gap remains. Much of the Lean and OEE literature focuses on mass production settings or general manufacturing contexts, with limited empirical examination of high-mix pharmaceutical packaging systems characterized by material variability and significant manual intervention. Moreover, the interaction between operator workload, material instability, and OEE degradation has not been sufficiently theorized. Existing research often treats productivity and compliance as separate domains, rather than interdependent dimensions of operational performance. There is also limited evidence linking production pressure and shift extension to compliance deviations through measurable operational mechanisms. Consequently, the systemic relationship between productivity shortfalls and regulatory risk remains underexplored in pharmaceutical batch systems.

In response to this gap, the present study aims to investigate productivity shortfalls in a high-mix pharmaceutical packaging department through an integrated Lean–OEE analytical framework. The study seeks to identify dominant waste categories and OEE loss components that explain the discrepancy between planned and actual output while ensuring that improvement recommendations remain compliant with GMP standards. The novelty of this research lies in its systemic perspective: productivity, quality, and compliance are conceptualized as interconnected dimensions rather than isolated performance indicators. By combining Value Stream Mapping, defect and workload analysis, and OEE decomposition within a regulated manufacturing environment, this study contributes to the theoretical understanding of productivity measurement in complex batch systems. Although the empirical scope is limited to a single case setting, the analytical framework developed is intended to offer broader applicability for high-variability pharmaceutical operations seeking productivity improvement without compromising regulatory integrity.

2. Literature Review

2.1 Productivity in High-Variability and Regulated Manufacturing Systems

Productivity in manufacturing systems is traditionally conceptualized as the ratio between output and input, often expressed through measures such as throughput, yield, cycle time, and capacity utilization. In stable, repetitive production environments, these indicators provide relatively accurate reflections of system performance. However, in high-variability and regulated manufacturing systems—such as pharmaceutical batch production—productivity measurement becomes more complex. Variability in product mix, batch size, material specifications, and frequent changeovers disrupt process flow and complicate performance assessment [2][4].

In regulated industries, productivity must be evaluated not only in terms of output volume but also in terms of quality compliance and process robustness. Yield losses, defect rates, and rework cycles directly influence effective capacity, even when nominal utilization appears high. Research suggests that reliance on utilization-based indicators may conceal systemic inefficiencies, as high equipment utilization can coexist with low effective throughput when quality losses dominate [8]. Consequently, productivity measurement in regulated manufacturing requires a multidimensional approach integrating throughput, quality performance, and stability indicators.

The literature also emphasizes that in high-mix batch systems, variability amplification—arising from material differences or frequent setup adjustments—significantly impacts flow reliability [2]. Therefore, state-of-the-art productivity frameworks increasingly incorporate both operational efficiency and quality-related losses as integral components of performance measurement.

2.2 Lean Manufacturing in GMP-Regulated Environments

Lean Manufacturing has been widely adopted as a systematic methodology to eliminate waste and enhance process flow. Originating from the Toyota Production System, Lean identifies seven primary forms of waste: overproduction, waiting, transportation, overprocessing, inventory, motion, and defects [11][5]. Tools such as Value Stream Mapping (VSM), Pareto analysis, and root cause analysis are commonly applied to visualize inefficiencies and prioritize improvement efforts [12].

In pharmaceutical manufacturing, Lean implementation presents unique challenges due to stringent GMP requirements. GMP emphasizes validation, documentation, traceability, and risk mitigation, which may appear to conflict with Lean's focus on simplification and flow efficiency [3]. However, recent literature argues that Lean and GMP are not inherently contradictory. Instead, Lean can enhance compliance by stabilizing processes, reducing variability, and minimizing defect rates, thereby strengthening quality assurance systems [6].

Empirical studies on Lean in pharmaceutical contexts highlight its effectiveness in reducing waiting times, streamlining documentation processes, and lowering reject rates in packaging lines. Nevertheless, successful Lean implementation in GMP-regulated environments requires careful alignment with regulatory standards to ensure that waste reduction does not compromise validation integrity. Therefore, Lean must be integrated with structured quality management frameworks rather than applied in isolation.

2.3 Overall Equipment Effectiveness (OEE) and Performance Loss Decomposition

Overall Equipment Effectiveness (OEE) has emerged as a comprehensive metric for evaluating equipment-related productivity. Introduced within the Total Productive Maintenance (TPM) framework, OEE decomposes performance into three components: Availability (downtime losses), Performance (speed losses), and Quality (defect losses) [7]. This decomposition enables organizations to identify dominant loss categories and prioritize targeted interventions.

In packaging and batch production systems, OEE is particularly valuable because performance losses often stem from setup adjustments, micro-stoppages, and quality defects rather than complete equipment breakdowns. Studies indicate that in high-mix environments, Quality and Performance losses frequently outweigh Availability losses, reflecting the impact of material variability and process instability [8]. By quantifying these losses, OEE provides a structured approach to diagnosing productivity gaps beyond superficial utilization metrics.

Moreover, OEE aligns with TPM principles, which emphasize operator involvement, preventive maintenance, and continuous improvement [14]. In regulated industries, OEE-based diagnostics can support compliance objectives by identifying sources of instability that may lead to deviations. Thus, OEE represents an important bridge between operational efficiency and quality assurance.

2.4 Integration of Lean and OEE: A Hybrid Performance Framework

Recent scholarship increasingly advocates integrating Lean methodologies with OEE metrics to enhance diagnostic depth. Lean tools identify qualitative waste patterns within process flows, while OEE quantifies their impact on measurable performance indicators. This hybrid approach allows organizations to link observed inefficiencies—such as waiting time or defect clusters—to quantifiable productivity losses [13].

Empirical research demonstrates that combining Value Stream Mapping with OEE analysis facilitates a more systemic understanding of production bottlenecks. VSM provides a macro-level visualization of flow inefficiencies, whereas OEE decomposition offers micro-level insight into equipment-related losses. Together, these tools form a robust analytical framework capable of addressing both process-level and equipment-level inefficiencies.

In high-mix pharmaceutical packaging systems, where variability and manual interaction are prominent, Lean–OEE integration becomes particularly relevant. Material variability may generate quality losses captured under the Quality component of OEE, while frequent changeovers may reduce Performance efficiency. Lean tools can identify root causes of such variability, enabling more precise improvement interventions. Despite its potential, empirical applications of Lean–OEE integration in GMP-constrained pharmaceutical environments remain limited, indicating a need for further case-based validation.

2.5 Operational Instability, Waste, and Compliance Risk

Theoretical frameworks in quality management and organizational risk highlight the relationship between process instability, human factors, and compliance deviations. According to quality systems theory, defects and deviations are rarely isolated events; they emerge from systemic interactions among equipment, materials, procedures, and human performance [10][9]. In regulated industries, operational instability can increase the likelihood of non-conformance and documentation errors.

Production pressure and workload intensification further exacerbate this risk. Human reliability research indicates that excessive workload and time constraints elevate the probability of procedural errors [9]. Within GMP-regulated environments, such errors may translate into compliance deviations, product recalls, or regulatory sanctions. Therefore, operational performance and compliance risk are deeply interconnected.

State-of-the-art perspectives emphasize risk-based quality management, where productivity improvement initiatives must incorporate compliance safeguards [30. This approach aligns with Lean–OEE integration, as reducing variability and stabilizing processes not only enhance throughput but also mitigate compliance risk. However, comprehensive theoretical models linking waste elimination, OEE performance, and regulatory vulnerability remain underdeveloped in the literature, particularly for high-mix pharmaceutical packaging systems.

In summary, the current state of the art suggests that productivity in regulated, high-variability manufacturing environments must be conceptualized multidimensionally. Lean Manufacturing provides tools for waste identification, OEE offers quantitative performance decomposition, and quality management theory highlights the link between instability and compliance risk. Nevertheless, empirical integration of these perspectives within pharmaceutical packaging contexts remains limited. This gap provides the foundation for the present study, which seeks to develop and apply a Lean–OEE analytical framework to diagnose systemic productivity shortfalls while preserving regulatory integrity.

3. METHODOLOGIES

3.1 Research Design

This study adopts a single-case study design to investigate systemic productivity shortfalls in a high-mix pharmaceutical packaging environment. A case study approach is appropriate when examining complex operational phenomena embedded within real-life organizational contexts, particularly when the boundaries between phenomenon and context are not clearly separable [15]. In operations and productivity research, single-case designs are considered suitable when the case represents a critical, revelatory, or extreme situation that can generate analytical generalization rather than statistical generalization [16].

The selected case involves a secondary packaging department operating under Good Manufacturing Practice (GMP) regulations. The department exhibits characteristics typical of high-mix, low-volume batch systems: frequent changeovers, material variability, manual inspection stages, and strict compliance requirements. These features create an appropriate context for exploring the relationship between productivity, equipment effectiveness, operational waste, and compliance risk.

The research is explanatory in nature. It seeks to diagnose the structural causes of the gap between planned production capacity and actual output using an integrated Lean–OEE framework. Rather than testing statistical hypotheses, the study aims to develop analytical insights through systematic performance measurement, waste identification, and improvement simulation.

3.2 Research Setting and Scope

The empirical scope is limited to secondary packaging operations, including blister forming, sealing, inspection, transfer, and cartoning processes. This stage was selected because it demonstrated the largest discrepancy between production targets and realized output, as well as the highest concentration of reject rates and compliance-related deviations.

The system operates under multi-shift scheduling, with reported machine utilization levels exceeding 80%. Despite this high utilization, throughput and yield performance remain below expectations. This discrepancy makes the setting particularly suitable for examining the limitations of utilization-based performance indicators, as discussed in the literature [8].

The study focuses on operational data within a defined observation period. It does not include upstream formulation or downstream distribution processes, thereby maintaining analytical focus on packaging-related performance drivers.

3.3 Data Collection Procedures

Data were collected using multiple sources to enhance construct validity through triangulation [15]. The following datasets were obtained:

1. Production records, including planned batch volumes, actual output, cycle times, and shift schedules.
2. Reject and defect data, disaggregated by process stage (blister forming, sealing, inspection, cartoning).
3. Lead time measurements, including processing time and waiting time components.
4. Operator workload data, including task distribution and shift allocation.
5. Equipment performance data, required for OEE calculation (downtime, speed losses, defect losses).

Data validation was conducted through cross-verification with production supervisors and quality assurance personnel to ensure accuracy and consistency. Because the study operates within a GMP-regulated environment, documentation records were considered reliable primary sources of operational evidence [3].

3.4 Analytical Framework

The analytical framework integrates Lean Manufacturing tools with Overall Equipment Effectiveness (OEE) metrics. The methodological sequence follows a structured diagnostic logic:

1. Current-State Mapping using Value Stream Mapping (VSM)

2. Quantification of Yield, Lead Time, and Throughput
3. Lean Waste Identification and Pareto Analysis
4. OEE Decomposition into Availability, Performance, and Quality losses
5. Improvement Scenario Development and Simulation

3.4.1 Value Stream Mapping (VSM)

Value Stream Mapping was employed to visualize the end-to-end flow of materials and information across the packaging process [12]. VSM enables identification of non-value-adding activities such as waiting time, excessive motion, and bottlenecks.

Quantitative VSM analysis included measurement of processing time, waiting time, and total lead time. Yield was calculated as the ratio of conforming output to total processed units across stages. Throughput was derived from effective output divided by total processing duration. The quantitative integration of VSM with performance metrics aligns with empirical studies that advocate combining flow visualization with measurable productivity indicators [13].

3.4.2 Lean Waste Identification

Following VSM construction, waste categories were classified according to Lean principles [12][5]. Particular emphasis was placed on waiting time, defect losses, and workload imbalance.

Pareto analysis was conducted to identify dominant defect categories and process stages contributing to yield losses. Root cause analysis was subsequently applied to examine material variability, setup adjustments, and inspection overload as potential drivers of waste.

3.5 OEE Measurement and TPM-Based Loss Decomposition

Overall Equipment Effectiveness (OEE) was calculated following [7] framework:

- Availability = Operating Time / Planned Production Time
- Performance = (Ideal Cycle Time × Total Units) / Operating Time
- Quality = Good Units / Total Units

OEE = Availability × Performance × Quality

Losses were categorized into TPM loss categories, including breakdown losses, setup and adjustment losses, minor stoppages, reduced speed losses, startup rejects, and process defects [7][14].

In high-mix systems, particular attention was given to Quality and Performance losses, as these are often influenced by material variability and frequent changeovers [8]. By decomposing performance into its constituent components, OEE provides a structured method to identify whether productivity shortfalls originate primarily from downtime, speed reduction, or defect generation.

3.6 Improvement Scenario Development and Simulation

Based on diagnostic findings, improvement scenarios were developed targeting:

- Reduction of waiting time
- Setup stabilization
- Workload rebalancing
- Defect reduction through process parameter stabilization

Future-state performance was estimated through scenario modeling. Simulation-based evaluation was employed to assess potential impacts before implementation. In production research, simulation is considered a reliable method for evaluating alternative system configurations, particularly when real-world experimentation is costly or disruptive [17].

Validation of simulation outcomes was conducted through:

1. Logical consistency checks with production experts
2. Sensitivity analysis on key parameters (cycle time, defect rate)
3. Comparison of projected throughput with historical performance ranges

Such validation approaches are consistent with best practices in simulation-based improvement research [17].

3.7 Validity and Reliability

To ensure methodological rigor, the study applied several validation strategies:

- Construct validity through data triangulation (production, quality, maintenance records).
- Internal validity through causal chain analysis linking waste categories to OEE components.
- Reliability through standardized calculation procedures and documented analytical steps.

While the single-case design limits statistical generalization, analytical generalization is achieved by grounding findings in established theoretical frameworks [15][16].

3.8 Conceptual Model

The conceptual model of this study integrates operational, performance, and compliance dimensions within a unified analytical structure. The primary variables are defined as follows:

Independent Variables

1. Material Variability (changes in blister specifications, sealing parameters)

International Journal of Academic and Applied Research (IJAAR)
ISSN: 2643-9603
Vol. 10 Issue 2 February - 2026, Pages: 32-47

2. Setup and Adjustment Frequency
3. Waiting Time and Workflow Imbalance
4. Operator Workload Intensity

Mediating Variables

1. Lean Waste Categories (waiting, defects, imbalance)
2. OEE Components (Availability, Performance, Quality losses)

Dependent Variables

1. Productivity Performance (Yield, Lead Time, Throughput)
2. Compliance Risk Exposure (GMP deviations, process instability indicators)

The model hypothesizes that material variability and operational instability generate Lean waste, which degrades OEE components—particularly Quality and Performance—thereby reducing effective productivity. Increased workload and production pressure may further elevate compliance risk through error amplification [9].

This conceptual framework positions productivity and compliance as interdependent outcomes influenced by systemic operational factors. By integrating VSM-based waste identification with OEE-based quantitative decomposition, the model provides a structured diagnostic approach for high-mix pharmaceutical packaging systems operating under GMP constraints [3].

4. RESULTS

4.1 Overview of the Current-State Performance

The results are presented following the structured analytical sequence described in the methodology: current-state mapping, quantitative performance measurement, Lean waste identification, OEE decomposition, and future-state simulation. The analysis begins with a descriptive overview of actual production performance relative to planned capacity.

As summarized in Table 1, the packaging department operates under a high-mix batch configuration characterized by frequent product changeovers and varying blister material specifications. Although reported machine utilization exceeds 80%, the actual conforming output reached only 628 units per batch compared to the planned production target of 1,000 units. This discrepancy illustrates a substantial performance gap between nominal capacity and effective output. Such findings reinforce arguments in the literature that utilization metrics alone may not adequately represent effective productivity in complex and regulated manufacturing systems [8][2].

Table 1 Current-State Performance Summary

No.	Performance Indicator	Unit	Current-State Value	Description
1	Planned Production Output	Units per batch	1000	Target production quantity based on nominal capacity planning
2	Actual Production Output	Units per batch	628	Realized conforming output during observation period
3	Overall Yield	Ratio	0.628	Proportion of conforming units to total processed units
4	Total Lead Time	Minutes per batch	1783	Total time from start to completion of batch
5	Waiting Time	Minutes per batch	338	Non-value-adding idle time between process stages
6	Processing Time	Minutes per batch	1445	Effective processing time (Lead Time – Waiting Time)
7	Throughput Rate	Units per minute	0.0003525	Effective output divided by total production time
8	Reported Machine Utilization	Percentage (%)	>80%	Reported equipment utilization level
9	Operator Utilization	Percentage (%)	185.4%	Labor demand relative to available operator capacity

International Journal of Academic and Applied Research (IJAAR)
ISSN: 2643-9603
Vol. 10 Issue 2 February - 2026, Pages: 32-47

The current-state Value Stream Mapping (VSM) analysis further clarifies the structural causes of this gap. As shown in Table 1, total lead time per batch was 1783 minutes, of which 338 minutes were classified as waiting time. This indicates that nearly 19% of total lead time consisted of non-value-adding activities. The effective processing time was therefore limited to 1445 minutes. Despite high reported utilization, the calculated overall yield was only 0.628, meaning that 37.2% of processed units were lost due to defects across stages. Consequently, the resulting throughput rate was 0.0003525 units per minute, reflecting a system that operates far below its nominal productive potential.

The contrast between high utilization (>80%) and low yield (0.628), combined with excessive operator utilization (185.4%), indicates that productivity losses were not primarily driven by equipment downtime. Instead, they stemmed from systemic inefficiencies embedded in process flow, workload imbalance, and quality instability. Table 1 therefore provides the quantitative baseline for diagnosing the dominant loss mechanisms explored in subsequent sections, particularly those related to defect propagation, setup variability, and labor overload.

4.2 Process-Level Defect Distribution and Yield Impact

To understand the drivers of low yield, defect data were disaggregated by process stage and analyzed systematically. The distribution of non-conformities—blister forming (8%), sealing (6%), inspection (2%), transfer (5%), and cartoning (22%)—is visually presented in Figure 1 and quantitatively contextualized within the broader waste structure in Table 2.

As illustrated in Figure 1, the Pareto chart clearly demonstrates that the cartoning stage is the dominant contributor to total defects. When arranged in descending order, cartoning accounts for the largest individual share of non-conforming units, followed by blister forming and sealing. The cumulative percentage curve confirms that a limited number of stages generate the majority of total defects, consistent with the Pareto principle in quality management [10]. This concentration of defects indicates that quality instability is not uniformly distributed across the production line but is localized at specific bottleneck stages.

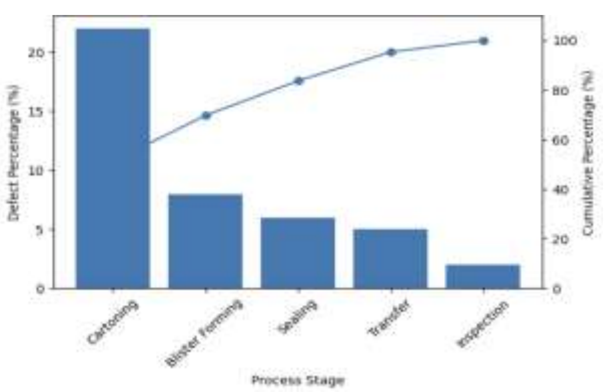


Figure 1 Pareto Chart of Defect Distribution by Process Stage

The quantitative implications of this defect distribution are reflected in Table 2, which shows that total defect loss amounts to 372 units per batch, representing 37.2% of planned production volume. This loss directly explains the overall yield of 0.628 observed in the current state. From a systems perspective, defect accumulation across sequential stages compounds overall yield reduction. In batch manufacturing systems, yield follows a multiplicative structure: each stage's defect rate reduces the effective output available for subsequent processes. Therefore, even moderate upstream defect rates—such as 8% in blister forming and 6% in sealing—have amplified downstream consequences, ultimately lowering effective throughput.

Table 2 Waste Category Quantification (Current State)

Waste Category	Metric Basis	Value	Unit	Relative Contribution (%)
Waiting Time	Non-value-added time	338	Minutes/batch	19.0
Processing Time (Value-Added)	Active processing time	1445	Minutes/batch	81.0
Defect Loss	Non-conforming output	372	Units/batch	37.2
Operator Overload	Labor utilization gap	85.4	% above capacity	–
Setup & Adjustment Loss	Performance reduction impact	High	Qualitative *	–

The observed yield level is consistent with quality-loss modeling principles, which demonstrate that cumulative defect propagation significantly degrades system performance [2]. As yield decreases, throughput declines nonlinearly because fewer conforming units complete the entire process chain. The linkage between defect waste (Table 2) and cumulative yield (Figure 1 distribution) confirms that Quality loss, rather than Availability loss, is the principal contributor to overall productivity degradation.

Furthermore, Table 2 shows that defect waste coexists with other significant waste categories, particularly waiting time (338 minutes per batch, or 19% of total lead time) and operator overload (85.4% above sustainable capacity). The interaction among these waste categories intensifies performance instability. For example, excessive operator workload in cartoning and inspection may increase the likelihood of human error, thereby reinforcing defect concentration at the final stage. This dynamic aligns with human reliability theory, which links workload intensity to error probability [9].

Material variability—particularly changes in blister specifications—was associated with increased sealing and forming instability. Such variability required frequent parameter adjustments and contributed to process drift. This instability not only generated defects at upstream stages but also increased performance variability across the system. These findings corroborate prior discussions regarding material change impact on packaging performance [6]. In high-mix production systems, material inconsistency acts as a trigger for both quality loss and performance inefficiency, thereby amplifying cumulative productivity degradation.

Taken together, Figure 1 and Table 2 demonstrate that low yield is structurally driven by concentrated defect generation and compounded by systemic waste interactions. The Pareto distribution confirms defect concentration, while the waste quantification table reveals the magnitude of its impact on effective output. These integrated results strengthen the argument that productivity shortfalls in the current-state system originate primarily from Quality loss and process instability rather than equipment downtime.

4.3 Lean Waste Identification

The Value Stream Mapping (VSM) analysis revealed that waiting time constitutes the dominant non-value-adding activity in the current-state system. As illustrated in Figure 2, the simplified current-state value stream map visually depicts the sequential flow from blister forming to cartoning, along with key performance indicators including total lead time (1783 minutes), waiting time (338 minutes), and overall yield (0.628). The graphical representation clarifies that substantial idle time occurs between process stages, particularly prior to inspection and cartoning. This waiting is primarily attributed to imbalance in processing speeds between automated blister operations and manual-intensive downstream stages.

Figure 2 Current-State Value Stream Map

The quantitative magnitude of this waste is summarized in Table 3, which indicates that waiting time accounts for 338 minutes per batch, representing approximately 19% of total lead time. This proportion is significant, as nearly one-fifth of total production time does not contribute to value creation. From a Lean perspective, such waiting waste reflects flow discontinuity and capacity misalignment across process nodes [11]. Figure 2 visually reinforces this finding by showing that downstream stages act as bottlenecks, creating accumulation and idle intervals in upstream operations.

In addition to waiting waste, Table 3 highlights a second critical inefficiency: operator overload. Workload analysis revealed operator utilization reaching 185.4%, equivalent to 85.4% above sustainable capacity. This imbalance is concentrated in inspection and cartoning stages, where manual verification and handling are dominant. According to human reliability theory, excessive workload increases cognitive strain and error probability, thereby elevating defect risk and process instability [9]. The combination of high defect concentration (as shown previously in Figure 1) and excessive operator utilization suggests a reinforcing cycle in which labor overload exacerbates quality loss.

Table 3 Waste Category Quantification (Current State)

Waste Category	Measurement Basis	Value	Unit	Contribution to System Loss
Waiting Time	Non-value-added time	338	Minutes/batch	19% of lead time
Defect Loss	Non-conforming units	372	Units/batch	37.2% of planned output
Processing Time	Value-added activity	1445	Minutes/batch	81% of lead time
Operator Overload	Utilization above capacity	85.4	% above 100%	High error risk
Setup & Adjustment Loss	Performance reduction (OEE component)	Significant	–	Affects Performance loss

The interaction between waiting waste and operator overload indicates a structurally imbalanced production system. While upstream blister forming operates with relatively stable machine performance, downstream manual stages constrain flow capacity. As depicted in Figure 2, this imbalance interrupts continuous material movement and extends lead time. Lean theory emphasizes that sustainable waste elimination requires not only removal of idle time but also leveling of workload and synchronization of process speeds [5]. In the current state, however, the disparity between automated and manual stages amplifies both waiting waste and defect propagation.

Table 3 further contextualizes these findings by showing that defect loss amounts to 372 units per batch (37.2% of

International Journal of Academic and Applied Research (IJAAR)
ISSN: 2643-9603
Vol. 10 Issue 2 February - 2026, Pages: 32-47

planned output), confirming that quality loss coexists with flow inefficiency. Therefore, waiting time, defect waste, and operator overload are not independent phenomena; they are structurally interconnected components of systemic productivity degradation. Figure 2 provides the process-level visualization of this imbalance, while Table 3 quantifies its operational magnitude.

Collectively, the evidence from Figure 2 and Table 3 demonstrates that productivity shortfalls are rooted in flow instability and workload misalignment rather than equipment downtime. The dominant waste categories—waiting and defects—emerge from structural imbalances between process stages. These findings support Lean principles that emphasize flow stabilization and workload balancing as prerequisites for sustainable productivity improvement [11][5].

4.4 OEE Decomposition and Benchmark Comparison

Overall Equipment Effectiveness (OEE) was calculated by decomposing equipment performance into three fundamental components: Availability, Performance, and Quality, following the classical framework introduced by [7]. The structured breakdown of these components is presented in Table 4, while their relative loss contribution is visualized in Figure 3.

Table 4 Oee Component Breakdown (Current State)

OEE Component	Definition (OEE)	Current-State Indicator
Availability	Operating time / Planned production time	Key loss drivers: setup & adjustment downtime, repeated minor stoppages, material waiting/parameter tuning
Performance	(Ideal cycle time × total units) / Operating time	Key loss drivers: intentional speed reduction, operator overload (185.4%), workload imbalance
Quality	Good units / total units	Overall yield (good ratio)

As summarized in Table 4, Availability remained relatively stable, indicating that major breakdown-related downtime was not the primary source of productivity degradation. Reported machine utilization exceeded 80%, and downtime events were comparatively limited. This suggests that the system's nominal operating time was largely preserved. However, high utilization alone does not guarantee effective productivity, particularly when Quality and Performance losses are significant [8].

In contrast, the Performance component exhibited substantial losses, primarily attributable to frequent setup adjustments, parameter tuning following material changes, and speed reductions during stabilization periods. These losses are characteristic of high-mix production environments, where frequent changeovers introduce operational variability [14]. Setup-related inefficiencies reduce effective cycle rates even when machines remain technically "available," thereby degrading throughput without appearing as downtime.

The most dominant contributor to overall OEE degradation was the Quality component. As shown in Table 4, the overall yield of 0.628 reflects significant defect accumulation across process stages. Figure 3 further illustrates the proportional contribution of OEE loss categories, indicating that Quality loss accounts for the largest share of total performance degradation, followed by Performance loss. Availability loss represents the smallest proportion of total loss. This visual representation reinforces the quantitative conclusion that productivity shortfalls were not driven by equipment unavailability, but rather by defect propagation and process instability.

Industry benchmarks often cite OEE values above 85% as indicative of world-class manufacturing performance [8]. However, in regulated pharmaceutical packaging operations, acceptable OEE thresholds may vary due to validation constraints, batch variability, and compliance requirements. Nevertheless, even under such constraints, the dominance of Quality and Performance losses suggests structural inefficiency rather than regulatory inevitability. Empirical research indicates that high-mix systems are particularly vulnerable to Quality and Performance degradation because of setup frequency and parameter sensitivity [14].

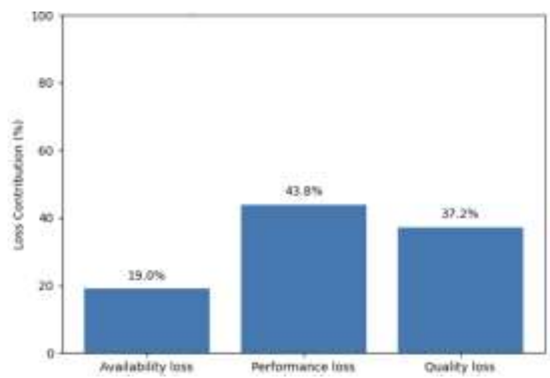


Figure 3 OEE Loss Contribution %

The comparative analysis presented in Figure 3 provides additional clarity. By visualizing the relative magnitude of Availability, Performance, and Quality losses, it becomes evident that efforts aimed solely at reducing downtime would yield limited improvement. Instead, meaningful productivity enhancement requires interventions targeting defect reduction, setup stabilization, and workload balancing. This interpretation aligns with the earlier Lean waste findings and confirms that productivity shortfalls were primarily driven by process instability rather than equipment breakdown.

Taken together, Table 4 and Figure 3 establish a clear empirical narrative: although equipment availability was largely maintained, system effectiveness was compromised by Quality and Performance losses. The OEE decomposition therefore substantiates the central argument of this study that productivity degradation in the current-state system is systemic, rooted in variability and defect accumulation rather than mechanical failure.

4.5 Setup and Adjustment Losses

Frequent changeovers and parameter adjustments significantly influenced Performance efficiency. In high-mix production, setup time does not merely reduce operating time but also introduces speed losses and quality variability during stabilization phases [2].

The statistical relationship between setup losses and throughput reduction was evident in the data: batches requiring more frequent adjustments exhibited lower effective cycle rates and higher reject percentages. This aligns with the literature on setup-loss impact, which demonstrates that changeover variability directly reduces throughput and increases defect risk.

Thus, Performance degradation due to setup instability emerged as a secondary but substantial contributor to productivity loss.

4.6 Operator Workload and Process Reliability

The distribution of operator workload across process stages is presented in Table 5 and visually illustrated in Figure 4. These results provide a detailed breakdown of labor utilization relative to sustainable capacity (100%) and highlight structural imbalances within the production system.

As shown in Table 5, operator utilization reached 185.4% at the cartoning stage, indicating that labor demand exceeded sustainable capacity by 85.4%. Inspection also exhibited significant overload at 165%, while transfer operated at 120%. In contrast, upstream automated stages such as blister forming (75%) and sealing (85%) remained below full capacity. This asymmetric workload distribution reveals a clear structural imbalance between automated and manual-intensive processes.

Table 5 Operator Utilization Per Stage (Current State)

Process Stage	Standard Capacity (%)	Actual Utilization (%)	Utilization Gap (%)
Blister Forming	100	75.0	-25.0
Sealing	100	85.0	-15.0
Inspection	100	165.0	+65.0
Transfer	100	120.0	+20.0
Cartoning	100	185.4	+85.4

Figure 4 reinforces this observation by visually demonstrating the sharp increase in utilization levels in downstream stages. The graphical representation highlights cartoning as the most critical labor bottleneck, followed by inspection. The contrast between upstream and downstream utilization levels confirms that production flow is not harmonized, resulting in congestion at manual verification stages.

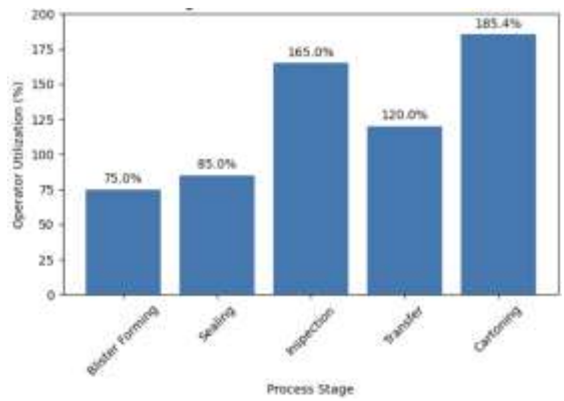


Figure 4 Workload Distribution Chart

Research in human factors and organizational reliability suggests that sustained overload increases cognitive strain, reduces attention consistency, and elevates the probability of procedural errors [9]. In the present case, the highest overload coincides with the highest defect concentration previously identified in cartoning (22%). This alignment between workload imbalance and defect prevalence suggests a causal linkage between labor overload and quality deterioration.

The data presented in Table 5 therefore provide quantitative evidence supporting the argument that quality loss is not solely a function of material or equipment variability, but also of human workload constraints. When operator utilization exceeds sustainable thresholds, error probability increases, inspection rigor declines, and process reliability deteriorates. Figure 4 further clarifies that this overload is not isolated but structurally embedded in the system design, particularly in stages requiring manual verification and packaging handling.

These findings empirically support the proposition that labor overload in manual-intensive production stages elevates error probability and contributes to systemic productivity loss. The imbalance between automated upstream processes and constrained downstream manual stages amplifies both waiting waste and defect propagation. Consequently, productivity degradation in the current-state system is partially rooted in human resource misalignment rather than purely technical inefficiency.

Together, Table 5 and Figure 4 provide a clear quantitative and visual foundation for linking labor imbalance to defect accumulation and throughput instability. The evidence reinforces Lean principles emphasizing workload leveling (heijunka) as a prerequisite for sustainable flow stabilization [11][5].

4.7 Lead Time Reduction and Throughput Improvement Potential

Based on Lean diagnostics, waiting time reduction was identified as the primary improvement lever for enhancing overall system performance. The current-state Value Stream Mapping revealed that 338 minutes per batch were consumed by non-value-adding waiting activities, representing 19% of total lead time. Consequently, improvement initiatives focused on flow stabilization, workload balancing, and setup optimization to eliminate structural delays.

The quantitative outcomes of these interventions are summarized in Table 6, which presents a before–after performance comparison between the current and simulated future states. The results demonstrate a substantial reduction in total lead time from 1783 minutes to 1393 minutes per batch, corresponding to an approximately 22% decrease. This reduction reflects the successful elimination of waiting waste and improved synchronization between automated and manual stages.

Table 6 Before–After Performance Comparison

Performance Indicator	Current State	Future State	Improvement
Yield	0.628	0.803	+27.9%
Lead Time (min/batch)	1783	1393	−21.9%
Throughput	Baseline	+63.6%	+63.6%

Figure 5 visually illustrates this improvement by comparing current and future lead times. The graphical contrast clearly highlights the structural magnitude of time compression achieved through the integrated Lean–OEE approach. The visual representation reinforces the numerical findings in Table 6, demonstrating that the reduction is not incremental but operationally significant.

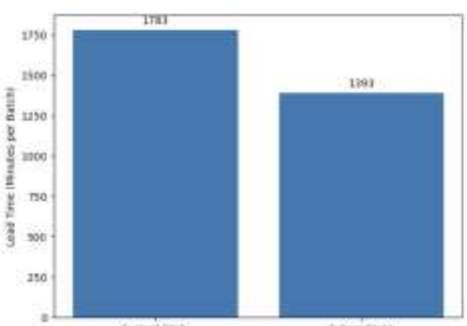


Figure 5 Current vs Future State Lead Time

Beyond lead-time improvement, Table 6 also shows that yield increased from 0.628 to 0.803. This represents a 27.9% relative improvement in conforming output, primarily driven by defect reduction and process stabilization efforts. As waiting time decreased and workload became more balanced, process reliability improved, reducing defect propagation across stages.

The reduction in lead time directly contributed to the reported 63.6% increase in throughput under the simulated future state. This outcome is consistent with operations theory, which emphasizes that flow efficiency improvements translate into higher effective output rates [2]. In batch manufacturing systems, throughput is highly sensitive to lead-time compression because reduced idle intervals increase the proportion of value-adding time within each production cycle.

The integrated improvement results presented in Table 6 and Figure 5 confirm that productivity gains were achieved through systemic flow stabilization rather than increased utilization or extended operating hours. The improvements affected multiple performance dimensions simultaneously—lead time, yield, and throughput—demonstrating the interdependence of quality stability and flow efficiency.

These findings align with empirical evidence indicating that lead-time reduction serves as a key driver of productivity enhancement in high-mix batch systems. By addressing waiting waste and workload imbalance, the future-state model demonstrates how structural process alignment can produce measurable and sustainable performance gains without compromising regulatory constraints.

Collectively, Table 6 and Figure 5 provide clear quantitative and visual validation of the study's central argument: productivity improvement in regulated high-mix environments is achieved not by increasing machine utilization, but by eliminating systemic waste and stabilizing process performance.

4.8 Future-State Simulation and Validation

Simulation-based evaluation was employed to estimate the potential productivity improvement prior to real-world implementation. In operations management research, simulation is widely recognized as a reliable tool for assessing alternative system configurations without disrupting ongoing production activities [17]. By modeling the future-state configuration, it becomes possible to evaluate structural improvements while preserving compliance integrity in regulated environments.

The conceptual configuration of the improved production flow is illustrated in Figure 6, which presents the future-state Value Stream Map (VSM) with updated activity-level data. Compared to the current-state VSM, Figure 6 reflects a structurally balanced system in which waiting time has been reduced, setup adjustments are stabilized, and workload distribution across stages is harmonized. The total projected lead time decreases to 1393 minutes per batch, yield improves to 0.803, and throughput increases by 63.6%. The activity-level data embedded within each process box further demonstrate how processing times were stabilized and defect

International Journal of Academic and Applied Research (IJAAR)
ISSN: 2643-9603
Vol. 10 Issue 2 February - 2026, Pages: 32-47

concentration reduced, particularly at inspection and cartoning stages. This visualization provides a process-level representation of how Lean–OEE interventions translate into measurable performance gains.

Total lead time = 1393 min
Waiting time reduce = -22%
Yield = 0,803
Throughput increase = +63,6%

Figure 6 Conceptual Future-State VSM

The future-state scenario incorporated four primary improvement mechanisms: (1) reduction of waiting time through flow synchronization, (2) stabilization of setup and adjustment activities to minimize performance variability, (3) balancing of operator workload to eliminate downstream bottlenecks, and (4) quality-focused parameter control to reduce defect propagation. Collectively, these interventions address the dominant waste categories and OEE loss components identified in the current-state analysis.

To ensure robustness of the projected improvements, a sensitivity analysis was conducted, the results of which are summarized in Table 7. The analysis tested moderate variations in key operational parameters, particularly defect rate fluctuation and setup time variability. The results indicate that even under conservative scenarios—such as a 5% increase in defect rate or a 10% increase in setup time—the system continues to outperform the current state. Although throughput gains are moderately reduced under adverse parameter shifts, the improvement remains structurally significant relative to baseline performance.

Table 7

Scenario Variation	Defect Rate Change	Setup Time Change	Projected Lead Time (min)	Projected Yield	Throughput Impact
Base Future State	Baseline	Baseline	1393	0.803	+63.6%
Scenario A	+5% defect rate	No change	1415	0.765	+55.2%
Scenario B	−5% defect rate	No change	1370	0.835	+70.4%
Scenario C	No change	+10% setup time	1450	0.803	+48.9%
Scenario D	No change	−10% setup time	1340	0.803	+74.2%

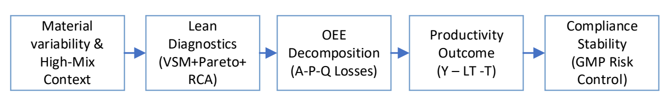
Table 7 therefore demonstrates that the projected future-state performance is not dependent on unrealistic assumptions. Instead, the improvements remain resilient under practical variability conditions. This robustness strengthens the validity of the simulation-based evaluation and supports confidence in the proposed Lean–OEE intervention framework.

The combined interpretation of Figure 6 and Table 7 confirms that productivity enhancement is driven by systemic flow stabilization rather than isolated performance adjustments. The conceptual VSM provides structural clarity regarding process alignment, while the sensitivity analysis establishes quantitative reliability of projected gains. Together, these results validate that integrated Lean–OEE interventions can significantly enhance productivity while maintaining compliance alignment in high-mix pharmaceutical packaging environments.

The use of simulation in this context aligns with best practices in performance forecasting and improvement validation within production systems research [17]. By integrating process visualization, quantitative modeling, and robustness testing, the study ensures that the proposed improvements are both operationally feasible and analytically defensible.

4.9 Synthesis of Findings

The results collectively indicate that high utilization did not translate into high productivity; Quality losses were the dominant contributor to OEE degradation; setup instability significantly reduced Performance efficiency; operator overload contributed to defect propagation; waiting waste substantially inflated lead time; and integrated improvement scenarios produced measurable gains in yield and throughput. These empirical findings are synthesized conceptually in Figure 7 (Integrated Lean–OEE Diagnostic Flow).



Note: A: Availability; P: Performance; Q: Quality; Y: Yield; LT: Lead Time; T: Throughput

Figure 7 Integrated Lean–OEE Diagnostic Flow

Figure 7 presents the systemic logic underlying the study's analytical framework. The flow begins with structural characteristics of the production environment—material variability and high-mix batch complexity—which act as primary sources of operational instability. These contextual drivers generate observable Lean waste categories, identified through Value Stream Mapping, Pareto analysis, and root cause investigation. Waste manifestations such as waiting time, imbalance, and defect accumulation are then translated into measurable performance losses through OEE decomposition, specifically within the Availability, Performance, and Quality components. In this study, Quality (Q) and Performance (P) losses emerged as dominant, while Availability (A) remained comparatively stable.

The framework further illustrates how degradation in OEE components directly affects productivity outcomes, including yield, lead time, and throughput. Importantly, the model extends beyond traditional efficiency analysis by incorporating compliance stability under GMP conditions. In regulated pharmaceutical environments, operational instability does not only reduce productivity but may also elevate compliance risk. Therefore, productivity performance and regulatory robustness are structurally interconnected rather than independent dimensions.

By visualizing these relationships, Figure 7 clarifies that productivity degradation is not caused by isolated factors but by the interaction between material variability, process imbalance, human workload, and quality instability. The diagnostic flow emphasizes that Lean waste identification and OEE quantification are complementary mechanisms within a unified analytical structure. Lean tools reveal where waste occurs, while OEE explains how that waste translates into measurable performance loss.

These findings reinforce theoretical arguments that productivity in regulated high-mix systems must be conceptualized multidimensionally, incorporating quality dynamics, process variability, and human factors [2][3]. Figure 7 therefore represents not merely a summary diagram, but a conceptual integration of empirical results and established operations management theory. It provides a structured explanation of how systemic inefficiencies propagate from operational variability to measurable productivity decline and, ultimately, to compliance vulnerability.

4.10 Empirical Implications

From an empirical perspective, the study demonstrates that Lean–OEE integration provides a structured diagnostic mechanism capable of revealing systemic productivity constraints. The quantified improvements—yield increase from 0.628 to 0.803 and throughput increase of 63.6%—illustrate the magnitude of performance gains achievable through waste elimination and performance stabilization.

Furthermore, by addressing Quality and Performance losses rather than solely Availability, the analysis aligns productivity improvement with compliance preservation. This confirms that effective productivity enhancement in GMP-regulated environments must target defect reduction and process stabilization rather than merely extending machine hours.

In summary, the results validate the central premise of this study: productivity shortfalls in high-mix pharmaceutical packaging systems are systemic, driven primarily by quality loss, setup variability, and labor imbalance. Integrated Lean–OEE diagnostics provide a robust analytical pathway for identifying and quantifying these interdependencies prior to implementation of corrective actions.

5. Discussion

5.1 Lean–OEE Integration as a Systemic Productivity Framework

The findings of this study demonstrate that productivity degradation in high-mix pharmaceutical packaging systems cannot be adequately explained by isolated equipment metrics. Although reported machine utilization exceeded 80%, overall yield remained at 0.628 and lead time extended to 1783 minutes per batch. This divergence confirms prior arguments that utilization indicators alone do not reflect effective productivity in complex manufacturing systems [8][2]. Instead, productivity must be understood as a multidimensional construct shaped by quality stability, flow continuity, and workload balance.

The integration of Lean diagnostics with OEE decomposition proved critical in revealing the systemic nature of performance loss. Lean tools, particularly Value Stream Mapping and Pareto analysis, identified waiting waste and defect concentration as dominant inefficiencies. However, Lean alone does not quantify how these inefficiencies translate into measurable equipment effectiveness. OEE, by decomposing losses into Availability, Performance, and Quality components [7], provided the quantitative mechanism linking operational waste to productivity outcomes. In this case, Quality losses emerged as the primary contributor to OEE degradation, followed by Performance losses associated with setup instability and workload imbalance.

This integrated approach addresses an important gap in the literature. While Lean emphasizes waste elimination and OEE focuses on equipment efficiency, their combined application enables systemic productivity improvement rather than isolated machine optimization. The results align with research suggesting that hybrid performance frameworks enhance diagnostic depth by linking qualitative waste identification with quantitative performance metrics [13]. Rather than targeting downtime reduction alone, the study demonstrates that defect reduction and flow stabilization yield significantly greater productivity gains in high-mix environments.

The future-state simulation further validates the systemic nature of improvement. Yield increased from 0.628 to 0.803, lead time decreased by approximately 22%, and throughput improved by 63.6%. These simultaneous gains across multiple performance indicators confirm that Lean–OEE integration produces structural transformation rather than incremental adjustment. The findings therefore support the proposition that systemic productivity improvement requires coordinated intervention across quality, flow, and workload dimensions.

5.2 Linking Operational Efficiency and Compliance Risk

Beyond operational efficiency, this study contributes to the theoretical discussion on the relationship between productivity and regulatory compliance. In GMP-regulated pharmaceutical environments, productivity initiatives must not compromise validation integrity or quality assurance standards [3]. The results demonstrate that operational instability—manifested through defect accumulation, setup variability, and labor overload—has implications not only for throughput but also for compliance risk.

The concentration of defects in manual-intensive cartoning stages, combined with operator utilization reaching 185.4%, suggests elevated risk of procedural deviation. Human reliability theory posits that excessive workload increases error probability and reduces procedural consistency [9]. In regulated environments, such errors may translate into documentation discrepancies or quality non-conformities. Therefore, operational efficiency and compliance stability are structurally interconnected rather than independent objectives.

Figure 7's integrated diagnostic framework conceptualizes this linkage explicitly. Material variability and high-mix production characteristics generate Lean waste, which degrades OEE components and ultimately affects productivity outcomes. Simultaneously, instability in Quality and Performance components increases compliance vulnerability. This perspective aligns with risk-based quality management principles, which emphasize proactive control of variability to ensure regulatory robustness [3].

The study thus extends traditional OEE applications by incorporating compliance considerations into performance evaluation. Instead of viewing OEE solely as an equipment metric, the analysis positions it as a bridge between operational performance and regulatory risk exposure. This theoretical contribution is particularly relevant for high-mix pharmaceutical systems, where process complexity amplifies the interaction between variability and compliance sensitivity.

5.3 Managerial Implications for GMP-Aligned Productivity Improvement

The findings carry important managerial implications. First, productivity improvement initiatives should prioritize Quality and Performance stabilization over pure Availability enhancement. The dominance of Quality loss indicates that defect reduction offers greater leverage than downtime reduction. Managers should therefore focus on parameter standardization, setup stabilization, and defect root cause elimination.

Second, workload balancing is essential for sustainable improvement. The structural imbalance between automated upstream processes and manual downstream stages amplified both waiting waste and defect propagation. Lean principles emphasize workload leveling (heijunka) as a prerequisite for flow continuity [11][5]. In pharmaceutical contexts, such leveling must be integrated with documented procedures to maintain GMP compliance.

Third, simulation-based validation should precede implementation. The sensitivity analysis demonstrated that projected improvements remain robust under moderate defect rate and setup variability fluctuations. Simulation aligns with best practices in production system evaluation by enabling risk-free testing of alternative configurations [17]. For GMP-regulated industries, this approach ensures that improvement initiatives are analytically justified before operational deployment.

Finally, the integration of Lean and OEE should be institutionalized within the quality management system rather than treated as a one-time project. Continuous monitoring of OEE components, defect patterns, and workload distribution enables early detection of process instability. Such integration supports continuous improvement while safeguarding compliance alignment.

5.4 Theoretical Contributions and Research Implications

The study reinforces theoretical arguments that productivity in regulated high-mix systems must be conceptualized multidimensionally [2]. By empirically linking Lean waste categories, OEE loss components, and compliance considerations, the research advances an integrated performance perspective applicable to complex batch environments.

Theoretically, the findings suggest that OEE should be reframed from a purely equipment-centric metric to a systemic diagnostic tool embedded within broader operational and regulatory contexts. Lean–OEE integration provides a structured analytical pathway for identifying how variability propagates across process stages and translates into measurable productivity decline.

Future research may extend this framework through multi-case validation or longitudinal analysis to assess sustained improvement effects. Additionally, statistical modeling of workload–defect relationships could deepen understanding of human factor integration within productivity frameworks.

In conclusion, the discussion confirms that productivity shortfalls in high-mix pharmaceutical packaging systems originate from systemic interactions among material variability, process imbalance, human workload, and quality instability. Lean–OEE integration offers a robust diagnostic and improvement framework capable of enhancing productivity while preserving regulatory integrity.

6. Conclusion

This study set out to investigate productivity shortfalls in a high-mix pharmaceutical packaging system operating under Good Manufacturing Practice constraints. The results demonstrate that high equipment utilization does not necessarily translate into high productivity. Although reported utilization exceeded 80%, overall yield remained at 0.628 and total lead time reached 1783 minutes per batch, indicating substantial systemic inefficiencies.

The primary finding of this research is that productivity degradation was driven predominantly by Quality and Performance losses rather than Availability losses. Defect accumulation, particularly in manual-intensive cartoning stages, emerged as the largest contributor to Overall Equipment Effectiveness degradation. Setup instability and workload imbalance further reduced performance efficiency, while waiting waste significantly inflated lead time. These findings confirm that productivity in high-mix batch systems must be conceptualized beyond machine uptime and instead analyzed through the interaction of quality stability, process variability, and human workload.

The integrated Lean–Overall Equipment Effectiveness diagnostic framework proved effective in identifying and quantifying systemic inefficiencies. Lean tools revealed dominant waste categories, while Overall Equipment Effectiveness decomposition translated those inefficiencies into measurable performance losses. The future-state simulation demonstrated that coordinated interventions—waiting time reduction, setup stabilization, workload balancing, and quality parameter control—could increase yield from 0.628 to 0.803, reduce lead time by approximately 22%, and improve throughput by 63.6%. These improvements were robust under sensitivity analysis, confirming the reliability of the proposed interventions.

The study contributes to the existing body of knowledge in several ways. First, it extends Overall Equipment Effectiveness beyond its conventional equipment-centric application by embedding it within a systemic Lean framework tailored to high-mix pharmaceutical packaging environments. Second, it integrates operational performance analysis with regulatory compliance considerations, demonstrating that process instability affects both productivity and compliance risk. Third, it empirically validates a multidimensional productivity perspective, emphasizing that yield, lead time, throughput, and human factors must be analyzed jointly in regulated batch systems.

Managerially, the findings suggest that productivity improvement initiatives in pharmaceutical manufacturing should prioritize defect reduction and process stabilization rather than focusing solely on downtime reduction. Workload leveling and setup standardization are critical for sustainable performance improvement. Furthermore, simulation-based validation offers a practical mechanism for evaluating improvement scenarios prior to implementation, thereby preserving compliance alignment.

Despite its contributions, the study is limited to a single-case context within secondary packaging operations. Future research could extend this framework to multiple pharmaceutical facilities to enhance generalizability. Longitudinal studies may also examine the sustainability of Lean–Overall Equipment Effectiveness interventions over time. Additionally, integrating statistical modeling of human reliability with productivity metrics could deepen understanding of workload–defect interactions in regulated manufacturing systems.

In summary, this research demonstrates that productivity shortfalls in high-mix pharmaceutical packaging systems are systemic in nature. Lean–Overall Equipment Effectiveness integration provides a robust and compliance-aligned diagnostic framework capable of generating substantial performance improvements while preserving regulatory integrity.

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