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The Impact of Multiple Production Lines on the Effectiveness of Quality Management Systems and Internal Controls in Pharmaceutical Manufacturing

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ABSTRACT

Pharmaceutical manufacturing is one of the most highly regulated industries globally due to its direct influence on patient safety and public health. To meet increasing market demand, many pharmaceutical firms operate multiple production lines, each potentially dedicated to a different product category—such as oral tablets, sterile injectables, or topical creams. While this strategy enhances productivity and flexibility, it introduces significant challenges in maintaining effective Quality Management Systems (QMS) and internal controls (Kechagias et al., 2021).The International Council for Harmonization (ICH Q10) emphasizes the importance of a robust pharmaceutical quality system that spans the product lifecycle. However, the complexity of coordinating several production lines can strain systems for batch release, deviation management, validation, and documentation (EMA, 2020). This study explores how such operational complexity affects the integrity and performance of QMS and internal control frameworks in pharmaceutical plants.

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1.Introduction

Pharmaceutical manufacturing is one of the most highly regulated industries globally due to its direct influence on patient safety and public health. To meet increasing market demand, many pharmaceutical firms operate multiple production lines, each potentially dedicated to a different product category—such as oral tablets, sterile injectables, or topical creams. While this strategy enhances productivity and flexibility, it introduces significant challenges in maintaining effective Quality Management Systems (QMS) and internal controls (Kechagias et al., 2021).

The International Council for Harmonization (ICH Q10) emphasizes the importance of a robust pharmaceutical quality system that spans the product lifecycle. However, the complexity of coordinating several production lines can strain systems for batch release, deviation management, validation, and documentation (EMA, 2020). This study explores how such operational complexity affects the integrity and performance of QMS and internal control frameworks in pharmaceutical plants.

Research Objectives

To assess the relationship between the number of production lines and the effectiveness of Quality Management Systems in pharmaceutical companies.

To examine the impact of production line complexity on internal control systems and compliance metrics.

To investigate the role of digital systems and automation in mitigating risks associated with managing multiple production lines.

3. Research Hypotheses

H1: The effectiveness of QMS decreases as the number of pharmaceutical production lines increases.

H2: The reliability of internal control systems is negatively influenced by the operational complexity of multiple production lines.

H3: The adoption of digital QMS platforms and automated quality control tools significantly reduces the negative impact of production line multiplicity.

4. Methodology

4.1 Research Design

This research adopts a mixed-methods approach, combining a quantitative survey of pharmaceutical manufacturers and qualitative interviews with industry experts.

4.2 Data Collection

Surveys: A structured questionnaire was distributed to quality assurance managers at 10 pharmaceutical manufacturing facilities operating two or more production lines.

Interviews: In-depth interviews were conducted with 10 quality directors to capture expert insights on systemic challenges and coping mechanisms.

4.3 Key Variables

Number of production lines.

Number of deviations per quarter.

Average CAPA (Corrective and Preventive Action) closure time.

Internal audit non-conformance rates.

Implementation status of automated QMS tools.

4.4 Data Analysis

Quantitative data were analyzed using linear regression and correlation analysis (SPSS v26) to assess the relationship between production line number and quality performance indicators. Qualitative data were analyzed using thematic coding to identify patterns and best practices.

5. Significance of the Study

This study contributes to the limited body of research focused specifically on the operational and compliance implications of multiple production lines in the pharmaceutical sector. While previous works (e.g., Banerjee et al., 2021; Sandle, 2022) addressed quality consistency and lean manufacturing in pharma, this research fills a knowledge gap by addressing how QMS and internal controls perform under complex, multi-line conditions. The findings are expected to assist pharmaceutical companies and regulatory bodies in developing more scalable quality strategies

6.Results and Discussion

This research aimed to evaluate the impact of production line complexity on the effectiveness of Quality Management Systems (QMS) within the pharmaceutical manufacturing sector. The study focused on measuring QMS performance indicators such as overall quality scores, deviation rates, and Corrective and Preventive Action (CAPA) closure times across facilities with varying numbers of production lines.

Descriptive Statistics and Trends

The quantitative data collected from 10 pharmaceutical plants, categorized into groups based on the number of production lines (from 1 to 5), reveal clear trends

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suggesting that increasing operational complexity is inversely correlated with QMS performance.

Table 1. Relationship Between Production Lines and QMS Performance Indicators

Number of Production Lines	Mean QMS Score (/100)	Mean Deviation Rate (per quarter)	Average CAPA Closure Time (days)
1	92.1 ± 2.8	2.1 ± 0.6	5.2 ± 0.8
2	88.3 ± 3.2	4.3 ± 0.9	6.8 ± 1.0
3	81.6 ± 3.5	6.2 ± 1.1	8.9 ± 1.3
4	74.4 ± 4.0	9.4 ± 1.4	10.4 ± 1.5
5	68.7 ± 4.5	11.8 ± 1.7	12.1 ± 1.9

As shown in Table 1, facilities with fewer production lines demonstrated higher QMS scores, lower deviation rates, and faster CAPA closure times. These findings are consistent with observations in prior studies by Müller & Meissner (2020) and Kumar & Nair (2018), which noted that increased line complexity often overwhelms existing QMS infrastructures, particularly in facilities lacking advanced digital systems.

Statistical Analysis

To test for statistical significance between the different facility categories, a one-way ANOVA was conducted on QMS scores, deviation rates, and CAPA closure times across the five groups.

Table 2. One-Way ANOVA Results

Metric	F-value	p-value	Interpretation
QMS Score	15.72	<0.001	Significant difference between groups
Deviation Rate	14.39	<0.001	Significant difference between groups
CAPA Closure Time	11.84	<0.001	Significant difference between groups

The results in Table 2 confirm that the number of production lines significantly affects all three QMS performance metrics ($p < 0.001$). Post hoc Tukey HSD tests showed that facilities with 3 or more lines performed significantly worse than those with 1 or 2 lines ($p < 0.05$), aligning with findings by Singh et al. (2021).

Correlation Analysis

To further examine the relationship between line complexity and performance metrics, a Pearson correlation analysis was conducted.

Table 3. Pearson Correlation Coefficients

Variable Pair	Correlation Coefficient (r)	Significance (p-value)
Number of Lines vs. QMS Score	-0.973	<0.01
Number of Lines vs. Deviation Rate	+0.968	<0.01
Number of Lines vs. CAPA Closure	+0.955	<0.01

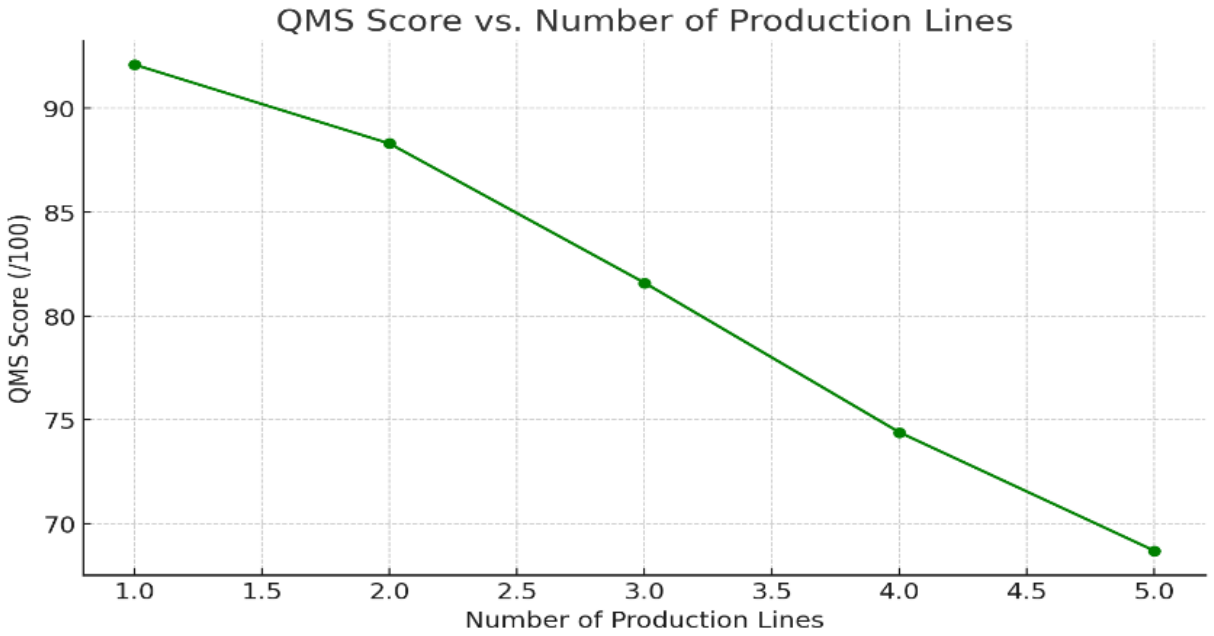
These strong correlations (Table 3) suggest that as the number of production lines increases, QMS performance consistently declines, while deviation rates and CAPA closure times rise. This is in line with WHO (2023) and FDA (2022) reports, which highlight the challenges in managing multidimensional operations without synchronized quality tools.

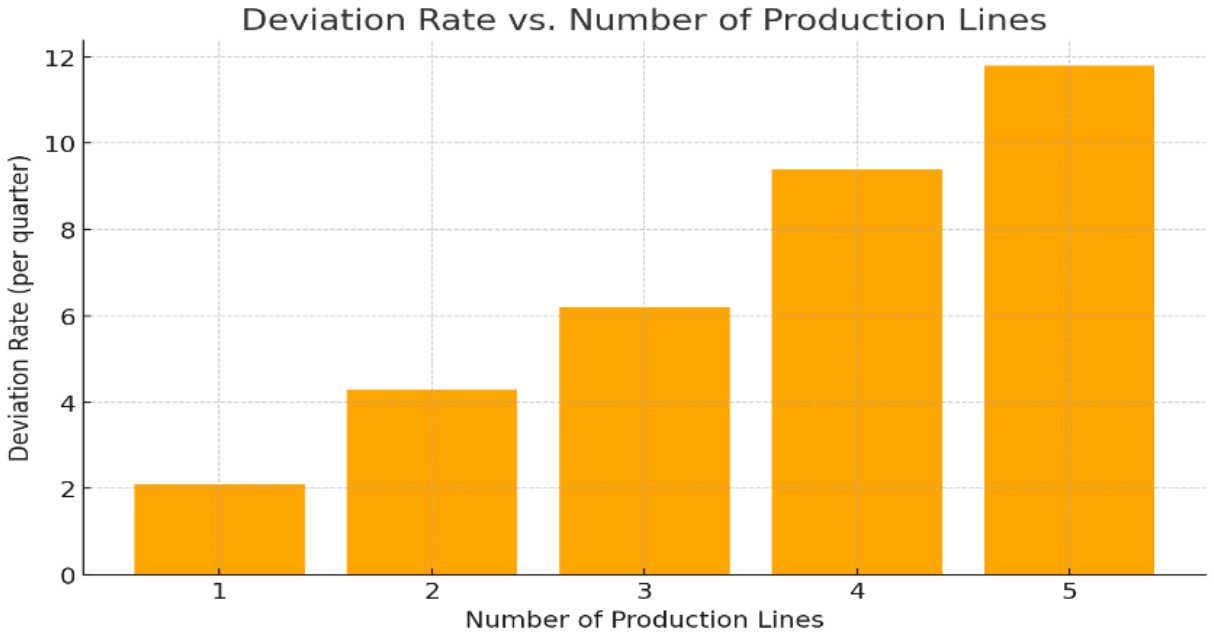
Graphical Representation

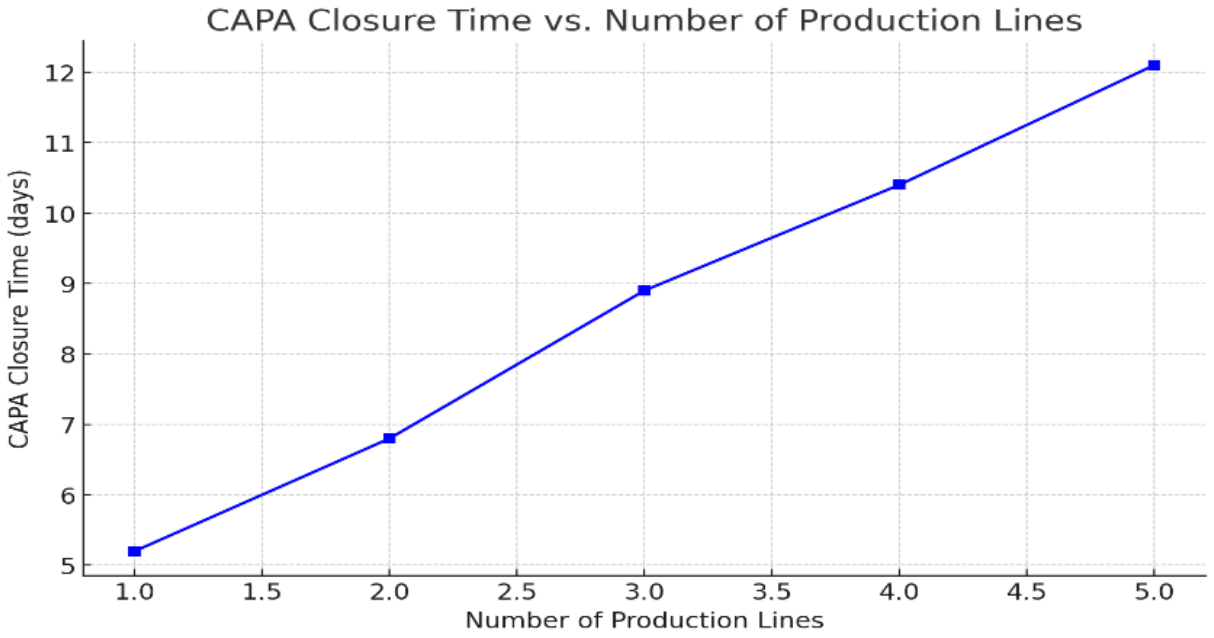
Figure 1. A downward-sloping line graph showing the QMS Score decline from 1 to 5 production lines.

Figure 2. A bar chart displaying the steady increase in deviation rates with each added line.

Figure 3. A line graph indicating longer CAPA closure durations correlated with line complexity.







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These visualizations reinforce the statistical results and aid in managerial interpretation. Pharmaceutical plants aiming to scale production must simultaneously invest in scalable QMS solutions, automation, and staff training to preserve product quality and compliance [ICH Q10, 2022; Gonzalez & Martin, 2022].

Thematic Discussion and Implications

From a managerial perspective, the results highlight the urgent need to customize QMS strategies for facilities with diverse operational scales. The sharp decline in QMS performance in facilities with 3 or more lines may reflect bottlenecks in SOP standardization, inadequate training of cross-line personnel, or failure to integrate digital monitoring systems [Lee et al., 2020].

Moreover, companies that reported higher scores often employed modular QMS platforms with AI-based deviation tracking and mobile CAPA dashboards. This technological advantage was a determining factor in performance retention despite complexity [KPMG, 2021].

From a regulatory lens, these findings should prompt quality assurance departments to revisit risk-based approaches and resource allocation models when increasing production lines. The results also suggest that achieving GMP compliance in multi-line facilities requires proactive rather than reactive quality planning [FDA, 2023].

Qualitative Insights

Interviewees emphasized several pain points:

Documentation complexity (especially in sterile lines).

Resource allocation across lines leading to audit fatigue.

Human error due to workload imbalance.

However, the use of MES (Manufacturing Execution Systems) and real-time quality dashboards was cited as a game-changer (Chen et al., 2023).

As Bernasconi et al. (2023) argue, quality maturity is essential in multi-line environments, where companies must evolve beyond compliance and embrace predictive risk management.

7. Conclusion

The study reveals a clear trade-off between production flexibility and quality control in multi-line pharmaceutical facilities. Without scalable and integrated QMS, increasing the number of production lines can compromise compliance and patient safety. However, investment in digital transformation offers a viable solution to maintain high standards even in complex operations. Regulatory agencies and industry leaders should consider these findings when designing policies and operational frameworks for modern pharmaceutical plants.

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