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Risk-Based Evaluation of Pharmaceutical Tablet Defects Using Failure Mode and Effects Analysis Before and After Process Improvement

Charles Onyeka Nwamekwe[1*], Raphael Olumese Edokpia[2]

[1] Department of Industrial and Production Engineering, Nnamdi Azikiwe University, Anambra State - Nigeria.
[2] Department of Production Engineering, University of Benin, Benin, Edo state - Nigeria.

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Corresponding Author:
Charles Onyeka Nwamekwe
co.nwamekwe@unizik.edu.ng

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Abstract: This study assessed pharmaceutical tablet-manufacturing risk before and after a coordinated process-improvement programme using Failure Mode and Effects Analysis (FMEA). It focused on identifying and ranking failure modes, comparing their Risk Priority Numbers (RPNs), and quantifying residual risk reduction for the AL-MAG 1050 mg tablet line at Alben Healthcare Industries Limited, Nigeria. A retrospective before-and-after industrial risk-evaluation design examined 100 production-batch and quality records from 2022 to 2024. Eight baseline FMEA entries were screened, with four matched failure modes retained: capping, lamination, moisture drift and tool wear. The intervention tightened granule-moisture, blending-time, compression-speed and compression-force windows alongside revised Standard Operating Procedures, process monitoring and tooling controls. Risk reduction was evaluated descriptively using paired RPNs, absolute change, percentage reduction and residual ranking. Capping (50.10%) and lamination (23.57%) dominated the baseline defect burden. Post-intervention RPNs decreased from 280 to 120, 240 to 110, 210 to 95 and 190 to 90, respectively. Reductions ranged from 52.63% to 57.14%, while the aggregate descriptive RPN index declined by 54.89%, from 920 to 415. Despite these improvements, the ranking remained unchanged, with capping retaining the highest residual priority. The findings support continued risk-based surveillance of compression-related failure mechanisms.

Keywords: Failure Mode and Effects Analysis (FMEA); Pharmaceutical Tablet Manufacturing; Process Improvement; Residual Risk; Risk Priority Number (RPN).

Introduction

In pharmaceutical tablet manufacturing, product quality and process consistency and regulatory compliance are tightly coupled and are governed by specific manufacturing conditions (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use [ICH], 2023). Evolution of the problem from a seemingly local deviation at the granulation, drying or compression stage could escalate into tablet capping and lamination, high friability, moisture instability or contamination, batch disposition, rework, production loss or quality assurance (World Health Organization [WHO], 2024; Alsaidalani & Elmadhoun, 2022). The observed quality issues in the AL-MAG tablet manufacturing process, Alben Healthcare Industries Limited, Nigeria were related to the condition of the equipment, compression setting, moisture content of granules, ambient conditions and the behaviour of the granules. Capping and lamination were of special concern as they were common occurrences and associated with compression and moisture control problems (WHO, 2024). Good Manufacturing Practice (GMP) stipulates that manufacturers manage these risks by having documented, traceable and scientifically justifiable

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quality systems. Risk assessment is not a post hoc analysis done after the batch has been rejected. It should differentiate between those failure modes that require immediate control and those that show relatively low operational exposure (ICH, 2023; Poli et al., 2024). Failure Mode and Effects Analysis (FMEA) offers a practical way of doing this by analysing the potential failure, causes and effects, and severity, occurrence and detection ratings. The three ratings are combined and assigned a Risk Priority Number (RPN) that provides a common basis to rank competing process risks. It is especially useful in tablet manufacturing to evaluate risk at two or more stages during the improvement process (Gül et al., 2020; Zheng & Tang, 2020). A baseline RPN defines the first exposure but does not indicate if the corrective action affected the risk profile. Reassessment Following Intervention serves as the missing evidence. Indicates if tighter process control, revised operating limits, maintenance actions, Standard Operating Procedure (SOP) changes and other corrective actions resulted in a decrease in the priority of an existing failure mode. This before/after reasoning is similar to the broader pharmaceutical need for ongoing process monitoring and control rather than a single problem resolution (Gül et al., 2020; Elmadhoun et al., 2025). In this particular instance, the improvement programme targeted the most significant tablet quality drivers, narrowed key operating windows and enhanced process controls. Granule moisture was narrowed from 1.5 to 4.5% to 2.0 to 3.0%, blending time from 6 to 18 min to 10 to 14 min, compression speed from 35 to 65 rpm to 40 to 55 rpm, and compression force from 7 to 13 kN to 8 to 11 kN. The revised SOPs, process monitoring and risk reassessment were then introduced in the control stage (Nwamekwe et al., 2026; Kendrick et al., 2024). This offers a suitable industry environment for quantifying if the process improvements resulted in a meaningful reduction in pharmaceutical manufacturing risk.

Defect structure of production line was not uniform. Approximately 50.1% of the recorded defect burden was due to capping and approximately 23.6% was due to lamination (Zheng & Tang, 2020; Kim & Park, 2022). The underlying mechanisms were traced primarily to compression conditions and equipment state and granule moisture. High compression speed, poor bonding, short dwell time and punch and die condition and moisture variation correlated with capping while entrapped air, suboptimal moisture and compression profile correlated with lamination (Yang et al., 2025; Liu et al., 2020). Nevertheless, the amount of manufacturing risk is not completely captured by frequency. Even a failure that occurs infrequently with a piece of equipment or as moisture failure, can be a concern if the consequences of the failure are significant or the piece of equipment has limited detection capability. The challenge here is that defect counts represent the location of loss, while FMEA represent the degree to which the loss is threatening to the process when severity, occurrence and detectability are combined, to create a practical analytical problem. This presents a practical analytical problem: defect counts tell where losses occur, while FMEA tell how strongly they threaten the process when severity, occurrence and detectability are put together (Gül et al., 2020; Nwamekwe et al., 2025a). The question to consider for management decisions is not just which defects happened, but how much the risk for each priority failure has been reduced or increased by the corrective action.

This study hence chooses the risk part of the broader programme of improvements in process and assesses the impact of it separately. Instead of modelling the whole machine-learning or Lean Six Sigma system, the analysis is limited to the priority failure modes and the measured FMEA risk before and after process improvement. The goal was to: (1) identify and rank the major failure modes that impact pharmaceutical tablet production; (2) compare the Risk Priority Numbers for the failure modes prior to process improvement and afterward; and (3) quantify the degree of risk reduction for the top failure modes.

Method

Study Design, Industrial Setting and Analytical Scope

A retrospective before-and-after industrial risk-evaluation design was adopted to examine changes in the risk priority of recurrent failure modes in pharmaceutical tablet manufacture following process improvement. The study was conducted on the AL-MAG 1050 mg tablet production line at Alben Healthcare Industries Limited, Nigeria. The process boundary covered granulation, drying, blending and tablet compression because these operations contained the principal material, environmental, equipment and process conditions associated with the defects considered in the risk assessment (Huang et al., 2020; Ohsaki et al., 2020). Compression force, compression speed, granule moisture, drying conditions and tooling state were particularly relevant to the observed capping, lamination and related quality failures. The source manufacturing database comprised 100 production batches and integrated Critical-to-Quality (CTQ) measurements, Critical Process Parameters (CPPs), defect and quality-control records, environmental observations, raw-material information, production logs, machine and operator records, measurement-system data and FMEA worksheets. The principal quality-control and defect dataset covered 15 January

2022 to 1 December 2024. Machine and operator records covered 1 to 15 April 2024, while the production-log component covered 1 May to 3 June 2024. These shorter datasets were used as contextual evidence within the wider batch-level data architecture rather than treated as the temporal boundary of the risk study. The study did not reproduce the broader machine-learning or Lean Six Sigma analysis. It isolated the risk-assessment evidence required to evaluate failure-mode priority before and after the implemented improvement programme. The study followed four analytical stages: baseline risk characterisation from the archived manufacturing evidence, introduction of the process-control package, six-month post-intervention monitoring, and comparison of the matched pre-improvement and post-improvement FMEA records. Because the archived source does not provide defensible calendar dates for every transition between these stages, no artificial intervention or reassessment date was assigned. The 2022 to 2024 manufacturing-data period and the documented six-month Control-phase monitoring period constitute the reproducible temporal frame for this analysis.

Data Sources, Failure-Mode Eligibility and Harmonisation

Risk information was triangulated across the FMEA worksheets, quality-control and defect logs, batch release and rejection records, process-parameter data, environmental monitoring records, maintenance and machine information, and production records. The original FMEA dataset contained eight records with process step, failure mode, potential cause, potential effect, Severity (S), Occurrence (O), Detection (D) and Risk Priority Number (RPN) (Peddapatla et al., 2021). The worksheets originated from the process team and used a 1 to 10 rating scale. The eight baseline FMEA entries were tablet capping, tablet lamination, high moisture content, poor granule flow, content non-uniformity, black-spot contamination, weight variation and incorrect labelling. Their recorded causes covered excessive compression speed, weak granules, worn tooling, high humidity, inadequate drying, raw-material moisture, blending deficiencies, hopper-feed instability and operator error. For the matched before-and-after assessment, a failure mode was eligible when: (i) it represented a documented tablet-quality or manufacturing-reliability risk; (ii) the later Control-phase FMEA contained a traceable corresponding risk category; and (iii) both pre-improvement and post-improvement RPN values were available. Four matched categories satisfied these requirements: capping, lamination, moisture drift and tool wear. Poor granule flow, content non-uniformity, weight variation and incorrect labelling were not included because equivalent post-intervention RPNs were not retained in the matched Control-phase summary. Their exclusion was based on lack of paired reassessment data and not on the direction or magnitude of their baseline risk.

Terminology was harmonised before the comparison because the Control-phase risk summary used broader categories for two of the original entries. The matching procedure is presented in Table 1.

Table 1. Harmonisation of Source and Matched FMEA Risk Categories

Matched category	Source risk concept	Principal process stage	Harmonisation basis
Capping	Tablet capping	Compression	Direct match of the same observable tablet defect
Lamination	Tablet lamination	Compression	Direct match of the same observable tablet defect
Moisture drift	High moisture content/moisture instability	Drying and granulation	Harmonised moisture-control category based on the documented drying and humidity mechanism
Tool wear	Tooling degradation associated with lamination and black-spot contamination	Compression	Harmonised equipment-degradation category based on documented punch/tooling-wear evidence

The distinction between the original FMEA input table and the later matched Control-phase FMEA was maintained throughout the analysis. The initial eight-record FMEA supplied the failure taxonomy, causes and contextual risk evidence, whereas the Control-phase table supplied the authoritative matched RPN Before and RPN After values used for the intervention comparison. This distinction prevents the original exploratory RPN values from being incorrectly substituted for the paired pre-intervention values.

FMEA Scoring Framework and Risk Evidence

Each failure mode was assessed according to the FMEA structure, which included the assessment of Severity, Occurrence and Detection. Severity was the rating of the possible negative impact of the product quality or patient safety was rated 1 to 10. Occurrence was defined in terms of the probability of the failure, from 1 for rare to 10 for frequent. The probability that the failure would pass through the current control system was termed detection and ranged from 1 (high detectability) to 10 (low detectability) (Nwamekwe et al.,

2025b). These definitions and directions have been carried over from the source methodology and are made without changes to the past.

For failure mode i, the Risk Priority Number was defined as

$$RPN_i = S_i \times O_i \times D_i \quad (1)$$

where S_i, O_i and D_i denote its Severity, Occurrence and Detection ratings, respectively.

The rating that was already recorded in the industrial FMEA records were used in this study. It did not conduct a new retrospective scoring exercise. It's crucial, because if a newly created scoring rubric or re-rating historical risks after learning the outcomes, it would bring unnecessary hindsight bias. The original FMEA worksheets were produced under the plant process-improvement structure and the broader programme engaged production, quality-assurance, maintenance/engineering and analytical staff in interpreting and reviewing processes for improvement. The source documentation indicates that the FMEA worksheets are process-team records, but there is not enough evidence to substantiate that all S, O and D scores were scored independently and consensus was established formally. The matched composite RPN values were also saved during the Control phase, but in this study, the individual post intervention S, O and D scores were not saved in the analytical summary. The end-to-end RPN was not factorised into its components; in fact, there are multiple different combinations of S, O, and D that can yield the same composite value (Lyytikäinen et al., 2022). This study, therefore, considers change in documented RPN priority, but does not attribute the observed reduction to a change in Severity, Occurrence or Detection.

Process-Improvement Package

The exposure of interest was the combination of the process improvement package that was introduced following the root cause investigation and process optimisation. The moisture content of the granules was reduced from 1.5-4.5% to 2.0-3.0, blending time decreased from 6-18 min to 10-14 min, compression speed was tightened from 35 rpm to 65 rpm to 40 rpm to 55 rpm and compression force was reduced from 7-13 kN to 8-11 kN. The analysis results from the preceding stages were translated into limits of operation on the shop floor. Changes to the Standard Operating Procedures (SOPs), process monitoring, maintenance and tooling controls, and Control-phase surveillance were provided as part of the parameter adjustments. As multiple corrective actions were implemented simultaneously, the intervention was considered as a package and not as individual interventions to examine the change in the various RPNs.

Table 2. Documented Risk Drivers and Corresponding Improvement Controls

Failure mode	Principal documented risk driver	Relevant improvement control
Capping	Compression speed, inadequate bonding, moisture variation, punch/die condition	Narrower compression-speed and force windows, tighter moisture control and tooling surveillance
Lamination	Entrapped air, granule-moisture imbalance, suboptimal compression profile, worn tooling	Moisture control, adjusted compression window and tooling-condition control
Moisture drift	High humidity, inadequate drying and residual-moisture variation	Narrower granule-moisture range and strengthened drying/environmental monitoring
Tool wear	Punch/die deterioration and wear-related contamination or compression instability	Maintenance review, tooling-condition surveillance and equipment-control actions

This mapping was grounded in the source root-cause analysis, which linked capping to compression and moisture control, lamination to the granulation-compression interface, and black-spot contamination partly to worn tooling.

Post-Intervention Risk Reassessment

Post-intervention risk evaluation used the same failure-mode directionality and RPN framework as the baseline assessment. The matched Control-phase summary preserved four pairs of documented RPN values: capping, 280 to 120; lamination, 240 to 110; moisture drift, 210 to 95; and tool wear, 190 to 90. These values were treated as observed industrial risk-assessment records and not as recalculated targets. A lower post-intervention RPN indicated a reduction in assessed priority. It did not, by itself, establish that the remaining risk was acceptable. Residual risk was interpreted separately because a failure mode can retain serious consequences even after its occurrence or detectability improves. The six-month Control-phase monitoring provided the sustainability context for the reassessment. The purpose of the comparison was therefore not to show that a risk score fell immediately after an SOP or set-point change, but to determine whether the documented risk profile remained lower after the improvement package had entered routine process control.

Risk Ranking and Quantification of Risk Reduction

The prespecified primary quantitative outcome was the percentage reduction in RPN for each matched failure mode. Secondary outcomes were absolute RPN reduction, pre-intervention and post-intervention rank, ranking stability, and change in the aggregate descriptive RPN index. At each assessment point, failure modes were arranged in descending order of RPN, with rank 1 representing the highest recorded priority. Equal RPN values were assigned tied ranks; no arbitrary tie-breaking procedure was applied (Bekaert et al., 2024).
Absolute RPN reduction was calculated as

$$\Delta RPN_i = RPN_{i,\text{before}} - RPN_{i,\text{after}} \qquad (2)$$

where $\Delta RPN_i > 0$ denotes a reduction in assessed risk priority.
Percentage RPN reduction was calculated as

$$RR_i(\%) = \frac{RPN_{i,\text{before}} - RPN_{i,\text{after}}}{RPN_{i,\text{before}}} \times 100 \qquad (3)$$

where RR_i represents the relative reduction for failure mode i.
For secondary descriptive comparison, the aggregate RPN index was calculated as

$$RPN_{\text{Agg,Before}} = \sum_{i=1}^{m} R\,PN_{i,\text{before}} \qquad (4)$$

and

$$RPN_{\text{Agg,After}} = \sum_{i=1}^{m} R\,PN_{i,\text{after}} \qquad (5)$$

where $m = 4$matched failure modes. Its percentage reduction was obtained from

$$RR_{\text{Agg}}(\%) = \frac{RPN_{\text{Agg,Before}} - RPN_{\text{Agg,After}}}{RPN_{\text{Agg,Before}}} \times 100 \qquad (6)$$

The aggregate index was treated strictly as a descriptive summary of the four paired RPN values. It was not interpreted as a continuous or additive measure of total pharmaceutical risk because RPN is formed from ordinal S, O and D ratings. Ranking stability was assessed by comparing the ordinal positions before and after intervention. An unchanged high-priority rank accompanied by a substantial RPN reduction was interpreted as reduced risk magnitude with persistence of the same dominant residual failure mechanism.

Statistical Analysis, Graphical Presentation and Reproducibility

The analysis was descriptive. No formal hypothesis test was applied to the four paired RPN values because the analytical unit comprised only four matched failure modes and the RPN is constructed from ordinal ratings. A paired *t*-test would incorrectly treat differences in RPN as interval-scale measurements, while a small-sample rank test would contribute little beyond the observed paired changes (Patel et al., 2023).

Analysis was performed for each failure mode and reported the pre-intervention RPN, post-intervention RPN, absolute reduction, percentage reduction and pre/post ranking. Values of RPNs were kept as whole numbers, while percentage reductions were given to two decimal points. Grouped before and after bar charts were used to visualise absolute RPN change and a second plot was used to show the percentage reduction by failure mode. The calculations were structured in Python 3.13.5, with pandas and NumPy for structured calculations, and Matplotlib for publishing quality graphics output. All values were tabulated and plotted in the same computational workflow to ensure that they came from a similar analysis script.

Since the paired composite RPN values were not recorded with the corresponding component ratings for the post-intervention phase, a component-level ΔS, ΔO and ΔD sensitivity analysis was not performed. To prevent this limitation, only documented changes in composite risk priority were used for inference, not reverse-engineering of unobserved ratings. The complete analytical code, calculation workflow and figure-generation script will be archived in the corresponding author's GitHub repository at the time of publication. The repository will include environment specification, the Python script used to calculate Equations (2) to (6), and the code required to reproduce the reported figures.

Data Integrity, Ethical Approval, Industrial Authorisation and Data Availability

Data handling followed the principles of Attributable, Legible, Contemporaneous, Original and Accurate plus Complete, Consistent, Enduring and Available (ALCOA+). Manufacturing, defect and risk records were retained under their source identifiers during the underlying study and were anonymised for analysis. No missing post-intervention RPN was imputed and no unmatched failure mode was assigned an estimated value. The broader research also incorporated measurement-system validation and calibration checks before downstream process analysis, reducing the likelihood that manufacturing variability was confused with measurement instability.

The study analysed industrial manufacturing and quality records and did not involve patients, clinical intervention or patient-level information. Formal ethical clearance for the underlying research was obtained from the university's institutional research ethics committee before data collection and model implementation. Non-disclosure and data-sharing agreements were established with Alben Healthcare Industries Limited to protect proprietary manufacturing information and intellectual property. The source dissertation records these approvals and supporting ethical documentation in its appendix.

The proprietary batch-level manufacturing records are not publicly distributable because of the industrial confidentiality agreement. For reproducibility of the present risk study, an anonymised analytical file containing the four matched failure-mode categories, pre-intervention RPNs, post-intervention RPNs and derived risk-reduction measures will accompany the reproducibility package. The executable analytical code will be made publicly accessible through the corresponding author's GitHub repository. No confidential formulation details, personnel identifiers, equipment identifiers or commercially sensitive production records will be included in the public repository.

This study design deliberately limits its claim to documented before-and-after change in FMEA risk priority. It does not treat RPN as a direct probability of product failure, infer missing S, O or D components, or attribute the recorded reductions to a single intervention where several process controls were introduced together.

Result and Discussion

Analytical Flow and Matched Risk Set

The analytical pathway reduced the wider industrial evidence base to the subset appropriate for paired risk evaluation. The source manufacturing database contained 100 production-batch records covering Critical-to-Quality characteristics, Critical Process Parameters, defects, environmental conditions, equipment, operator and supporting quality information. Eight baseline FMEA entries were available, but only four risk categories had traceable corresponding RPN values before and after the improvement programme. These were capping, lamination, moisture drift and tool wear.

The analytical chain from 100 production-batch and quality records to eight baseline FMEA entries to four defensibly matched failure modes is shown in figure 1. The staged workflow is also methodologically significant since it helps keep unmatched risks from becoming interventions' outcomes. Harmonisation comes before baseline RPN characterisation, which is followed by the implementation of the harmonisation improvement package, six-month monitoring, reassessment and final ranking. This encourages reflection and minimises the hindsight bias. Also, it explains that the reported reduction in risks relates to reported matched risks, not the full original set of FMEA risks. The figure thus establishes a single auditable before and after risk-evaluation pathway for regulated manufacturing decisions, between Objectives 1-3.

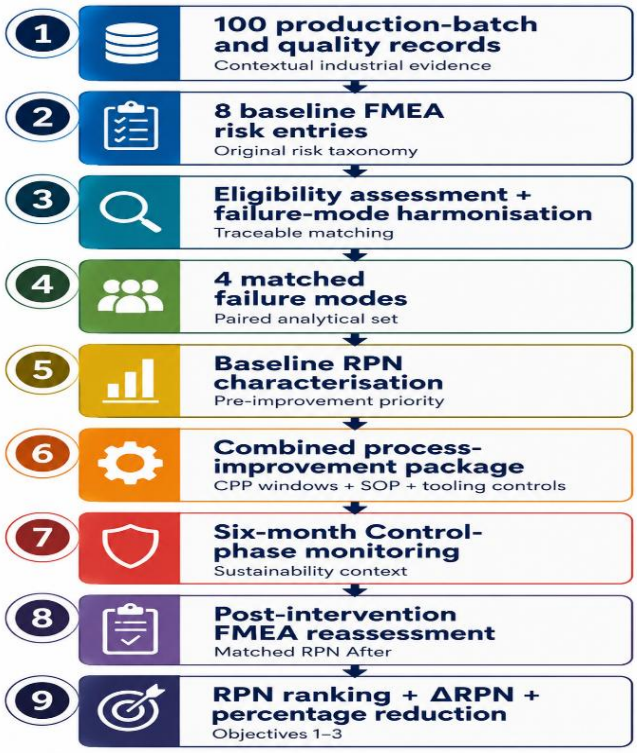


Figure 1. Analytical Workflow for the Before-and-After FMEA Risk Evaluation of the AL-MAG Tablet Manufacturing Process

Table 1 illustrates that the matched risk set was created by explicit tracing instead of just label replacement. The categories of capping and lamination are direct matches, but the others, moisture drift and tool wear, need to be harmonised due to the new terminology introduced during the Control-phase. Three of the four matched risks involve compression or its direct inputs, thus emphasizing the relationship of moisture state, compression mechanics and tooling condition. This is important from an analytical point of view because the study not only considers visual defect but also process mechanisms. The table also helps to prevent ambiguity in selection, as it illustrates how baseline concepts were assigned to similar post-intervention categories prior to the application of an RPN reduction.

Table 1. Harmonisation of Baseline FMEA Failure Modes with Matched Post-Intervention Risk Categories

Matched Failure Mode	Baseline Risk Concept	Principal Process Stage	Documented Failure Mechanism	Basis for Harmonisation	Eligibility for Paired Analysis
Capping	Tablet capping	Compression	Cap separation associated with compression speed, bonding, moisture and tooling condition	Direct match of the same observable tablet defect	Eligible
Lamination	Tablet lamination	Compression	Layer separation associated with entrapped air, moisture imbalance, compression profile and worn tooling	Direct match of the same observable tablet defect	Eligible
Moisture drift	High moisture content/ moisture instability	Drying and granulation	High humidity, inadequate drying and residual-moisture variation	Harmonised moisture-control category based on the documented drying and humidity mechanism	Eligible
Tool wear	Tooling degradation associated with lamination and black-spot contamination	Compression	Punch/die wear producing friction, compression instability or metallic debris	Harmonised equipment-degradation category based on documented tooling-wear evidence	Eligible

Base Line Defect Pattern and Failure-Mode Prioritisation

Overall, the distribution of their baseline defects was highly skewed. There were 4,365 recorded defects that were represented in the four main defect categories upon which the Pareto analysis was applied. Of the defects observed, 50.10% or 2,187 defects were attributed to capping. 23.57% of the defects were due to lamination. Mottling was responsible for 764 defects (17.50%) and black spots accounted for 385 defects (8.82%).

This meant that the contribution of capping and lamination was 73.68% of the defect burden recorded, or 3,216 defects. This gives a good empirical ground for focusing subsequent risk-control effort for compression related mechanisms, rather than spread it evenly across all defect categories. The result is also in agreement with the problem structure as described in this study, in which the most common recurring problems occurring under compression, were capping and lamination, both of which were linked to granule moisture and condition of equipment.

Figure 2 displays a very prominent baseline defect profile. The number of defects recorded is 4,365; capping alone accounts for 2,187 defects (or 50.10%) and lamination 1,029 defects (or 23.57%) which together make up 73.68% of all 4365 defects. The cumulative curve is not crossing 80% until mottling is included, whereupon it does reach 91.18%, indicating that the bulk of the defects are compression-related. This helps to reinforce the improvement effort, instead of a diffuse one. Importantly, the Pareto ranking is for frequency, not total risk. Capping and lamination are thus appropriate business priorities for this while FMEA is still required to account for severity and detection of lower frequency mechanisms like tooling degradation.

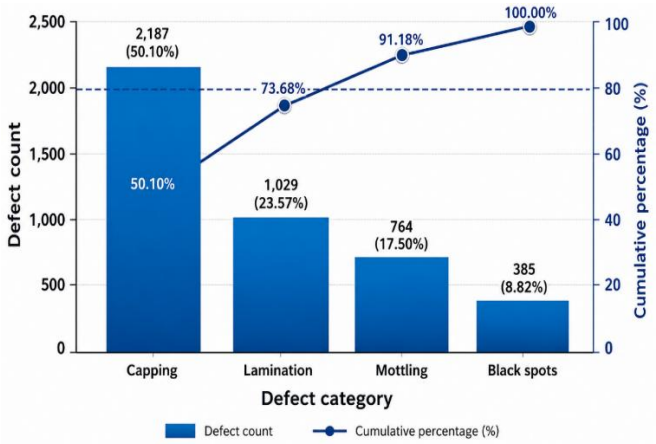


Figure 2. Pareto Distribution of Baseline Tablet Defects Used to Support Failure-Mode Prioritisation

Process-Improvement Controls Applied to the Priority Risks

The observed defect structure was translated into a process-control package rather than treated as a purely descriptive quality problem. Granule moisture was narrowed from 1.5–4.5% to 2.0–3.0%, blending time from 6–18 min to 10–14 min, compression speed from 35–65 rpm to 40–55 rpm, and compression force from 7–13 kN to 8–11 kN. These operating-window changes were accompanied by revised Standard Operating Procedures, tighter process monitoring and maintenance or tooling controls.

Table 2. Documented Risk Drivers and Process-Improvement Controls for the Matched Pharmaceutical Tablet Failure Modes

Failure Mode	Principal Documented Cause/Risk Driver	Process Stage	Pre-Improvement Control Weakness	Improvement Control Introduced	Intended Risk-Control Mechanism
Capping	Compression speed, inadequate bonding, moisture variation, punch/die condition	Compression	Wide compression/moisture windows and insufficient tooling surveillance	Compression speed 35–65→40–55 rpm; compression force 7–13→8–11 kN; granule moisture 1.5–4.5→2.0–3.0%; tooling surveillance	Reduce recurrence of compression-related cap separation and strengthen upstream control
Lamination	Entrapped air, granule-moisture imbalance, suboptimal compression profile, worn tooling	Compression	Broad moisture/compression windows and tooling-condition vulnerability	Moisture control; adjusted compression-force window; tooling-condition control	Stabilise the granulation-compression interface and reduce layer separation
Moisture drift	High humidity, inadequate drying and residual-moisture variation	Drying and granulation	Broad moisture acceptance range and environmental/drying variability	Granule moisture 1.5–4.5→2.0–3.0%; strengthened drying and environmental monitoring	Reduce moisture excursions and downstream CTQ instability
Tool wear	Punch/die deterioration, friction, wear-related contamination or compression instability	Compression	Reactive or insufficient tooling-condition surveillance	Maintenance review, tooling-condition surveillance and equipment-control actions	Detect and control tooling degradation before defect or contamination propagation

The engineering bridge used to connect between the risk drivers that are diagnosed and the intervention package is given as Table 2. Tighter compression and moisture control addressing capping and lamination, moisture drift addressed through drying, environmental monitoring and maintenance surveillance addressing tool wear. Corrective action was not just confined to end-product inspection, but was directed upstream at process mechanisms. This enhances the preventive value and matches the intervention with the formation of tablet defects through granulation, drying and compression. Cautious causal interpretations of the table are also possible: several of the controls were adjusted at the same time, therefore it is impossible to assign any decrease in RPNs after the intervention to any one adjustment of the controls.

Pre- and Post-Intervention RPN Comparison

Lower RPN values resulted from the paired FMEA comparison for all four failure modes that were matched. The Risk Priority Number (RPN) decreased from 280 to 120, corresponding to a reduction of 160 points (57.14%). The absolute decrease in lamination was 240-110 or a 130. Moisture drift was reduced from 210 to 95 (115), and tool wear was reduced from 190 to 90 (100). These are the values from the FMEA that are authoritative during the Control Phase and will be used for comparison when implementing the intervention.

Table 3. Pre- and Post-Intervention Risk Priority Numbers, Risk Rankings and Magnitude of Reduction for the Matched Failure Modes

Failure Mode	RPN Before	Baseline Rank	RPN After	Post-Intervention Rank	Absolute RPN Reduction (ΔRPN)	RPN Reduction (%)	Rank Change
Capping	280	1	120	1	160	57.14	0
Lamination	240	2	110	2	130	54.17	0
Moisture drift	210	3	95	3	115	54.76	0
Tool wear	190	4	90	4	100	52.63	0

The best quantitative evidence of risk reduction comes from Table 3. Capping fell from 280 to 120, lamination from 240 to 110, moisture drift from 210 to 95, and tool wear from 190 to 90. Absolute reductions were

between 100 and 160 RPN points, and proportional reductions were between 52.63% and 57.14%. The relative number of the four failure modes did not change, as the risk magnitude dropped significantly, but did not alter the order of the failures. Capping continued to be the number one remaining concern, despite making the greatest reduction. This distinction between improvement and residual priority is of the utmost importance for post intervention surveillance, and allows till no further actions are taken for control.

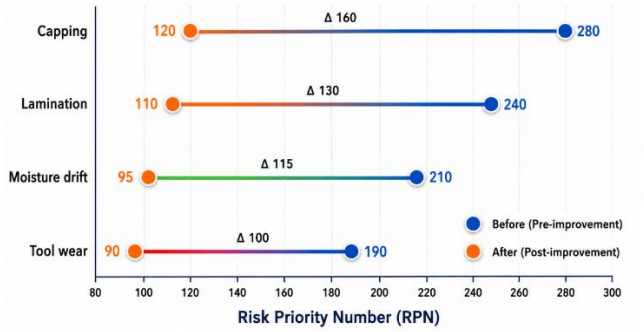


Figure 3. Paired Comparison of Risk Priority Numbers Before and After Process Improvement for the Four Matched Failure Modes

Figure 3 provides a graphic representation of the overall trend of the Risk Priority Number for each failure mode that was matched. The highest absolute gain is in the capping category which saw a 160-point drop, followed by lamination at 130, moisture drift at 115 and tool wear at 100. A straight comparison of the absolute gaps should not be interpreted as equivalent treatment effects, as this depends on the baseline RPNs. Cross-risk comparison is better achieved using proportional reductions. The same applies for the unchanged success order of endpoints: "capping" is the highest in the success column after "improvement", "lamination", "moisture drift" and "tool wear". So, exposure was measurably lowered, but not abolished, by the intervention, leaving the same underlying hierarchy of residual risks in need of ongoing control effort.

Magnitude of Risk Reduction and Residual Priority

Percentage reduction provided the primary quantitative measure of intervention response. Capping recorded the largest proportional reduction at 57.14%. Moisture drift followed at 54.76%, lamination at 54.17%, and tool wear at 52.63%.

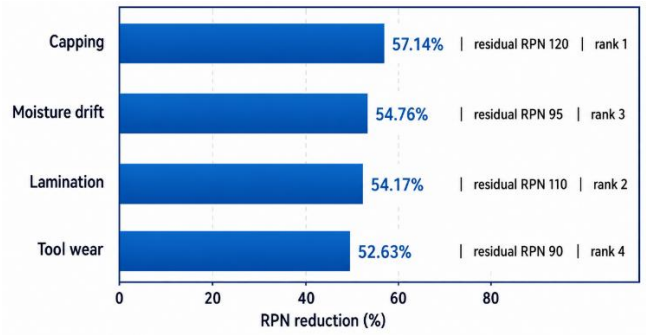


Figure 4. Percentage Reduction in Risk Priority Number and Residual Risk Ranking After Process Improvement

As seen in Figure 4, the proportional risk reduction was evenly distributed across the four matched failure modes with values ranging from 52.63% to 57.14%. Capping had the greatest decrease (57.14%), but had the highest residual RPN (120) and rank (1). Moisture drift improved by 54.76 % while lamination's moisture drift was 54.17 % with the residual moisture drift at rank 3. The smallest proportional improvement was recorded in tool wear, with a 52.63% improvement, but still having the lowest residual RPN of 90. The figure illustrates the relationship between percentage improvement and residual priority, explaining when the reduction in the highest-priority residual risk can be deemed great enough to relax the level of surveillance.

Aggregate Descriptive Risk Change

Table 4 summarizes the matched risk profile at system level (not replacing failure-specific interpretation). The aggregate descriptive RPN index dropped from 920 prior to intervention to 415 following intervention, a decrease of 505 points or 54.89% with the mean RPN dropping from 230.00 to 103.75. Capping, at 120, was the top failure in both, down from 280. The consistency across the aggregate reduction and the individual decreases suggests a widespread improvement pattern as opposed to isolated improvement. The aggregate index, however, should still be secondary as it is the sum of ordinal Severity, Occurrence and Detection scores. It is not a real measurement of the overall pharmaceutical risk, but rather a descriptive summary.

Table 4. Aggregate Descriptive FMEA Risk Index and Overall Risk-Reduction Summary Before and After Process Improvement

Assessment State	Number of Matched Failure Modes	Aggregate Descriptive RPN Index	Mean RPN	Highest-Priority Failure Mode	Highest RPN	Aggregate RPN Reduction	Aggregate Reduction (%)
Before	4	920	230.00	Capping	280	505	54.89
After	4	415	103.75	Capping	120		

Integrated Discussion Against the Research Objectives

The first was to identify and prioritise the most significant failure modes impacting the production of pharmaceutical tablets. The baseline defect evidence indicated that the defect burden of capping and lamination were dominant, accounting for 50.10% and 23.57% respectively, and 73.68% altogether. Lamination, moisture drift and tool wear all had a relatively high RPN at their baseline position, with all three risks being lower than the RPN of 280 for capping when the matched risks were taken into consideration through FMEA. The correlation between defect frequency evidence and FMEA ranking for limiting strength increases the argument for making the limiting strength a primary operational target when considering cap failure. FMEA provides information that is not available in defect counts, such as information about moisture drift and tool wear, which is a result of upstream process and equipment mechanisms.

The second goal was to make pre- and post-process improvement comparisons. Each matched failure mode had a lower post-intervention score, with decreases of 160, 130, 115 and 100 RPN points for capping, lamination, moisture drift and tool wear, respectively. The pattern suggests that the improvement cycle was related to a general reduction in the risk profile documented in the agreement, instead of improved performance in one risk category.

The third goal was to look at the degree of risk reduction. The percentage reductions were between 52.63 and 57.14 while the four-risk aggregate descriptive index was reduced from 920 to 415. The reaction to this was significant for the entire matched set. However, the remaining ranking didn't change. This is one of the more helpful findings of the study as it can be differentiated from risk reduction and risk elimination. Despite making the greatest percentage improvement, the greatest absolute risk reduction was with capping.

That is especially significant in regulated manufacturing. It is important to note that a lower RPN does not equate to an acceptable level of residual risk, it is merely evidence that the assessed process risk profile has been reduced. Residual acceptability ultimately remains based on the severity of the underlying failure, the level of residual control and the company's authorized quality-risk criteria. The present study thus reinforces the idea that the risk-control process should continue and not just be closed as soon as the numerical reduction of the RPN.

Practical Meaning of the Findings

The results indicate that the highest gain was seen when the risk assessment was reassessed with respect to controllable process conditions. Capping and lamination were not addressed simply at a post-filling stage by sorting end products. They used tighter compression and moisture windows in their control pathway combined with tooling surveillance. Earlier in the process moisture drift was dealt with by drying and controlling the environment. The wear of the tools was regarded as a problem of the machine's condition and was taken as a maintenance issue. This is a process-based interpretation which is critical as tablet defects are not always obvious in the manufacturing process. Any conditions that lead to capping or lamination could have been established during the granulation, drying or set-up of equipment and material conditioning process before capping or lamination is actually observed during compression or inspection. The risk reductions thus reinforce the operational benefits of controlling a source upstream as opposed to solely the source downstream. The study also shows that there is a practical compromise in the traditional RPN analysis. The composite score is a simple means of prioritising and pre and post comparison without giving a clear indication of the specific risk component that has been altered. The reduction in the archived post intervention data was not broken down by Severity and Occurrence and Detection so it would be unfair to say that the reduction resulted specifically from better detection or reduced occurrence. Thus, the present results should be interpreted as a reflection of lower composite rather than component level causal decomposition of documented risk priority.

Conclusion

The aim of this study was to determine if there was any change in pharmaceutical manufacturing risks following a coordinated process-improvement programme on AL-MAG 1050 mg tablet line in Alben Healthcare Industries Limited, Nigeria. The analysis intentionally narrowed the four categories of FMEA, namely: capping, lamination, moisture drift and tool wear, for which matched pre- and post-intervention RPNs were available. This limitation meant that ratings that were missing after the intervention were not reconstructed or intervention outcomes were not treated as missing post-intervention ratings. The baseline data indicated that failures were highly skewed towards compression related failures. Capping accounted for 2,187 defects, which were 50.10 % of the total defect burden; lamination accounted for 1,029 defects, which were 23.57 % of the total defect burden. They then cleared the way for compression, moisture and control in relation to the tools: They contributed 73.68% to the total. Based on updated Standard Operating Procedures along with process monitoring and tooling controls, all four process risks had lower RPNs after tighter windows for granule-moisture, blending-time, compression-speed and compression-force were applied. Capping

lessened by 120, lamination reduced to 110, moisture drift went from 210 to 95 and tool wear fell from 190 to 90. The reductions ranged from 52.63% to 57.14% and the aggregate descriptive RPN index decreased from 920 to 415 (a reduction of 54.89%). The ranking order was still the same, however. Even after intervention, capping remained in rank #1, followed by lamination, moisture drift, and tool wear. This distinction is relevant because the intervention resulted in an actual decrease in the magnitude of the risk, but did not take away the original residual-risk ranking. That continued surveillance should therefore stay focused on capping and other compression-related mechanisms and not be seen as a reduction in the number of risk-control actions automatically.

The scientific contribution of the study is twofold: it shows the importance of distinguishing defect frequency from risk priority in the evaluation of a pharmaceutical process; it shows the usefulness of this distinction from a practical perspective. The Pareto analysis revealed the failure mechanisms where the defects were concentrated, while the paired FMEA assessment revealed the priority of selected failure mechanisms after intervention. This distinction is significant as lower frequency risks, like tooling deterioration, may still have operational relevance when severity and detectability are taken into account. The study also offers a defensible approach for carrying out before-and-after FMEA analysis when the terminology used for the risks changes over time. Directly matched categories were kept as they were and moisture drift, as well as tool wear, were harmonised in a transparent manner based on the documented mechanisms of the processes. Industrially, the study demonstrates the usefulness of FMEA when corrective actions are related to controllable process conditions. The treatment focused on the compression behaviour, the moisture of the granules, the drying conditions and the state of the tools rather than primarily on downstream sorting or rejection. The overall decrease in all four of the matched RPNs demonstrates plant-level evidence of risk assessment as a continuous process-governance exercise, rather than a prioritisation exercise.

There are three main weaknesses in the study. First, there were only 4 of the 8 original FMEA risks that had defensible paired post-intervention RPNs. The conclusions are therefore limited to the matched set and cannot be used to infer that the problems of granule flow, content non-uniformity, weight variation or incorrect labelling have been solved. Second, the archive from Control-phase did not include the composite pre- and post-intervention ratings (Severity, Occurrence and Detection). The analysis is not able to distinguish between decreases in occurrence, increases in detection, not changing in severity, or a combination of these. If the missing ratings had been worked out in reverse, it would have been based on unsupported assumptions. Third, multiple process controls were added in the same improvement cycle to the design, limiting its ability to isolate the contribution of the individual process change, e.g., the effect of the adjustment of the compression speed, moisture control or tooling surveillance.

Future studies should keep all pre/post Severity, Occurrence and Detection histories, review all baseline failure modes and test extended monitoring periods for various products or manufacturing lines. A similar extension to other alternative risk-prioritisation methods that lessen the known limitations of multiplicative RPN scoring would enhance risk discrimination and provide better residual-risk governance.

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Author Contributions

For research articles with several authors, a short paragraph specifying their individual contributions must be provided. The following statements should be used "Conceptualization, CON. and ROE.; methodology, CON.; software, CON.; validation, CON, and ROE.; formal analysis, CON.; investigation, CON.; resources, CON.; data curation, CON.; writing—original draft preparation, CON.; writing—review and editing, ROE.; visualization, CON and ROE.; supervision, ROE.; project administration, ROE; funding acquisition, CON. All authors have read and agreed to the published version of the manuscript.

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Conflicts of Interest

The authors declare no conflict of interest.

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