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An Enhanced RPN Model Incorporating Maintainability Complexity for Risk-Based Maintenance Planning in the Pharmaceutical Industry

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Abstract

In pharmaceutical manufacturing, the reliability of machines and utility assets is critical to ensuring product quality, regulatory compliance, and uninterrupted operations. Traditional Risk-Based Maintenance (RBM) models quantify asset criticality using the Risk Priority Number (RPN), calculated from the probability and impact of failure alongside detectability. However, these models often neglect the practical challenges involved in diagnosing and resolving equipment issues, particularly in GMP-regulated environments. This study proposes an enhanced RPN framework that replaces the conventional detectability component with Maintainability Complexity (MC), quantified through two practical indicators: Ease of Diagnosis (ED) and Ease of Resolution (ER). Thirteen Key Performance Indicators (KPIs) were developed to assess Probability, Impact, and MC across 185 pharmaceutical utility assets. To enable objective risk stratification, Jenks Natural Breaks Optimization was applied to group assets into Low, Medium, and High risk tiers. Both multiplicative and normalized averaging methods were tested for score aggregation, allowing comparative analysis of their impact on prioritization outcomes. The enhanced model produced stronger alignment with operational realities, enabling more accurate asset classification and maintenance scheduling. A 3D risk matrix was introduced to translate scores into proactive strategies, offering traceability and digital compatibility with Computerized Maintenance Management Systems (CMMS). This framework provides a practical, auditable, and scalable approach to maintenance planning, supporting Industry 4.0 readiness in pharmaceutical operations.

Keywords: Risk-Based Maintenance (RBM); enhanced Risk Priority Number (RPN); maintainability complexity; asset criticality assessment; Key Performance Indicators (KPIs); pharmaceutical manufacturing; Jenks natural breaks optimization; maintenance strategy optimization; industry 4.0 maintenance; equipment diagnostics and resolution; maintenance scheduling

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Academic Editor: Wei Liang

Received: 10 September 2025
Revised: 26 September 2025
Accepted: 30 September 2025
Published: 2 October 2025

Citation: Al-Hourani, S.; Hassanlou, A. An Enhanced RPN Model Incorporating Maintainability Complexity for Risk-Based Maintenance Planning in the Pharmaceutical Industry. *Processes* **2025**, *13*, 3153. https://doi.org/10.3390/pr13103153

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1. Introduction

In the pharmaceutical industry, equipment reliability is not merely a matter of operational efficiency; it is a fundamental prerequisite for ensuring product quality, regulatory compliance, and patient safety. Failures in critical equipment or utility systems such as HVAC units, chillers, purified water loops, and compressed air networks can lead to production stoppages, violations of Good Manufacturing Practices (GMP), and significant financial and reputational damage [1].

To proactively manage these risks, pharmaceutical manufacturers often adopt Risk-Based Maintenance (RBM) strategies. RBM prioritizes maintenance tasks based on the likelihood and severity of equipment failure, typically quantified using the Risk Priority Number (RPN). The traditional RPN model is defined as the product of three factors: Probability of failure (P), Impact of failure (I), and Detectability (D) [2]. Despite its widespread application, the classical RPN framework suffers from several conceptual and practical shortcomings. Chief among these is the assumption that detectability adequately captures the operational burden of identifying and resolving equipment issues, an assumption that does not hold true in highly regulated environments [3,4].

In GMP-compliant settings, maintenance interventions are constrained by strict protocols, documentation requirements, and cleanroom access limitations. As highlighted in ICH Q9 (Quality Risk Management) [5] and ICH Q10 (Pharmaceutical Quality System) [6], effective risk assessment is essential to prevent misclassification of asset criticality and ensure proper resource allocation. Consequently, the time and resources needed to diagnose and resolve even routine equipment failures can be substantial. However, traditional RPN models do not incorporate this added layer of complexity into risk assessments, which can result in the misclassification of asset criticality and misallocation of maintenance resources [7,8].

To address this critical gap, we propose an enhanced RPN framework that replaces the detectability factor with a more operationally relevant dimension: Maintainability Complexity (MC). MC reflects the degree of effort required to diagnose and resolve equipment failures and is quantified using two practical indicators: Ease of Diagnosis (ED) and Ease of Resolution (ER) of failure. Each of the three dimensions (P, I, and MC) is assessed using structured Key Performance Indicators (KPIs), scored on a five-level ordinal scale, and validated by a cross-functional expert panel representing engineering, quality assurance, operations, and maintenance. This structured approach ensures consistency, traceability, and alignment with the GMP.

The proposed framework was applied to 185 utility assets within a multinational pharmaceutical facility. In contrast to arbitrary thresholding approaches, we employed Jenks Natural Breaks, a statistical clustering method, to segment assets into empirically derived risk tiers. To evaluate the influence of score aggregation methodology on risk stratification, we compared two strategies: multiplicative aggregation (mirroring the classical RPN logic) and normalized averaging (designed to reduce the influence of extreme values). This dual aggregation-clustering comparison, to the best of the authors' knowledge, has not been previously reported in the literature.

By integrating MC and data-driven clustering into the RPN framework, this study provides a more accurate and operationally meaningful basis for maintenance prioritization planning. The enhanced framework supports better alignment between technical risk and maintenance strategy, ensuring that resources are focused where they are most needed, and helping pharmaceutical manufacturers meet the evolving demands of Industry 4.0.

2. Literature Review

The RPN has served as a foundational element of RBM frameworks, particularly in regulated industries such as pharmaceuticals. Traditionally, the RPN was computed as the product of three factors: P, I, and D [9,10]. While this model is valued for its simplicity and widespread adoption, it suffers from significant conceptual limitations that undermine its accuracy and effectiveness in real-world applications, especially within GMP-compliant environments.

One core criticism of the classical RPN model is that its non-uniqueness different combinations of P, I, and D can yield the same RPN value, thereby masking the true criticality of

assets [3]. Furthermore, the "Detectability" dimension has been repeatedly questioned in its ability to reflect the practical burden of diagnosing and resolving failures [2]. In operational contexts characterized by stringent compliance requirements and limited access to critical areas, such as pharmaceutical cleanrooms, the detectability metric often fails to capture the full scope of challenges posed by maintenance tasks.

To address these shortcomings, researchers have proposed various methodological enhancements to the RPN model. These include fuzzy logic, Analytic Network Process (ANP), and hybrid models like DEMATEL-ANP, all of which aim to improve the subjectivity and interdependence handling within risk scoring systems [4,11]. However, these approaches, despite offering improved mathematical sophistication, rarely account for MC, which remains a blind spot in many existing RBM tools.

In highly regulated pharmaceutical environments, MC is a critical and often underrepresented factor. This refers to the degree of difficulty in diagnosing and resolving equipment failures, which is influenced by factors such as cleanroom constraints, procedural validation steps, and specialized tooling [7,8]. While post-failure metrics such as Mean Time to Repair (MTTR) and asset availability are commonly tracked [12], these measures do not proactively inform risk assessments, leaving a gap in maintenance planning and resource allocation.

Another critique of conventional RPN applications lies in the subjective classification of risk thresholds, such as the common "RPN > 100" cutoff. These thresholds often lack statistical justification and may misclassify asset criticality. As a response, data-driven clustering methods have gained traction as a more robust and statistically grounded approach for segmenting asset risk tiers based on actual variance in scoring distributions [13,14]. Such methods allow for empirical risk stratification that reflects true operational conditions.

In parallel, the advent of Industry 4.0 has introduced new requirements for RBM systems to integrate seamlessly with digital platforms, predictive analytics, and sensor-based monitoring. While these digital tools excel at predicting the timing of failures, they often neglect the complexity of resolution, thereby offering only a partial view of asset risk [15,16]. Integrating MC into RBM frameworks addresses this limitation, enabling smarter, resource-conscious maintenance planning that aligns with the digital transformation in manufacturing [1].

In summary, the literature reveals a consistent theme: while traditional RPN-based models provide a structured foundation for RBM, they fall short in capturing the real-world burdens of maintenance execution, particularly in pharmaceutical environments governed by compliance-driven operational constraints as shown in Table 1. By incorporating MC through structured KPIs such as ED and ER, and leveraging data-driven clustering techniques for risk categorization, the enhanced RPN model addresses long-standing gaps in precision, auditability, and strategic alignment. This evolution is not only timely but necessary to meet the multifaceted challenges of modern pharmaceutical asset management.

Table 1. RPN calculation in the literature review.

Method	Components Included	Formula or Aggregation	Typical Notes and Tradeoffs
Traditional multiplicative RPN	Severity (S), Occurrence (O), Detection (D)	RPN = S × O × D [17]	Simple and widespread; criticized for ties and lack of weights [18,19]
Weighted/composite FMECA	S, O, D plus maintenance cost, downtime, access, machine importance, etc.	Weighted sum or (sum of weighted factors) × modifier (e.g., access difficulty) [20]	Allows maintainability, cost and access to be explicit; requires weight-setting and validation [20]

Table 1. *Cont.*

Method	Components Included	Formula or Aggregation	Typical Notes and Tradeoffs
Fuzzy/FRPN approaches	S, O, D as fuzzy linguistic variables; may use weighted geometric mean or fuzzy inference [18,21]	FRPN via fuzzy weighted geometric mean or fuzzy inference rules, then defuzzification [18,21]	Handles assessor uncertainty and subjective judgments; reduces some RPN artifacts [18,21]
Probabilistic/DEA/ Monte-Carlo	S, O, D treated as probabilistic estimates or distributions; or evaluated via efficiency methods [22]	Probabilistic priority metrics or simulation-derived scores; DEA/Monte-Carlo combine criteria statistically [22]	Provides statistical meaning and confidence intervals; more complex and data-intensive [22]

3. Methodology

3.1. Framework Overview

This study presents an enhanced RBM framework aimed at optimizing preventive maintenance strategies for GMP-regulated pharmaceutical environments. The framework modifies the traditional RPN formulation by replacing the D dimension with MC, addressing a critical shortcoming in classical models. The enhanced model evaluates asset criticality based on three core dimensions: Probability of Failure (P), Impact of Failure (I), and Maintainability Complexity (MC).

Each dimension is assessed using a structured set of KPIs, scored on a five-point ordinal scale. The overall goal is to align maintenance planning with true operational risk by integrating statistical clustering, domain-specific KPIs, and a 3D criticality risk matrix.

A schematic representation of the framework and its deployment stages is shown in Figure 1.

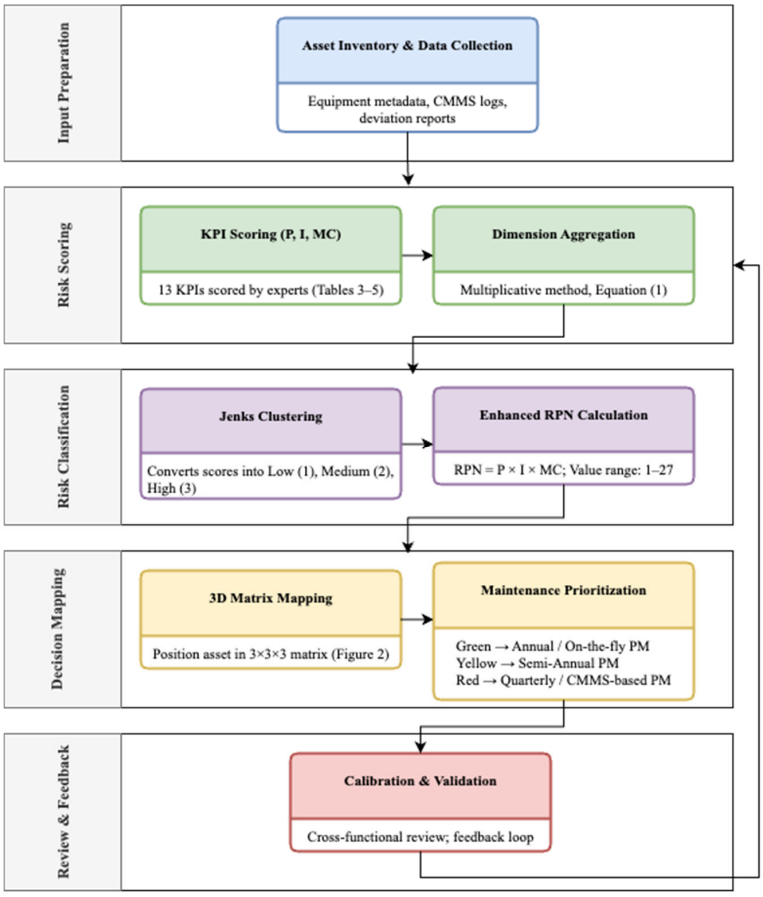


Figure 1. Schematic of Enhanced RPN Framework.

3.2. KPI Definition and Scoring

The framework utilizes 13 KPIs across three dimensions: P (3 KPIs), I (8 KPIs), and MC (2 KPIs). Each KPI was developed in consultation with cross-functional domain experts to reflect operational and regulatory concerns in pharmaceutical assets. Table references below summarize the KPIs and associated scoring criteria:

- Table 2: Definitions and classification levels for all KPIs;
- Table 3: Probability dimension KPIs (P1–P3);
- Table 4: Impact dimension KPIs (I1–I8);
- Table 5: Maintainability Complexity dimension KPIs (M1–M2).

Table 2. Definitions and classification levels for all KPIs.

Category	KPI	Description
Probability	Life Expectancy (P1)	Remaining useful life of equipment
	Failure Frequency (P2)	Number of failures in the last 12 months
	Condition (P3)	Physical state and reliability of the equipment
Impact	Safety & Health (I1)	Injury risk from equipment failure
	Environment (I2)	Environmental damage due to failure
	Alternative Availability (I3)	Backup systems or failovers available
	Product Quality (I4)	Effect on output quality
	GMP Compliance (I5)	Degree of impact on GMP protocols
	Production Time Loss (I6)	Downtime impact in h/days
	Maintenance Costs (I7)	Estimated financial cost of repair
	Utilization (I8)	Usage rate of equipment during production
Maintainability	Ease of Diagnosis (M1)	How easily the fault can be identified
	Ease of Resolution (M2)	Effort and time needed to fix the issue

Table 3. Probability dimension KPIs (P1–P3).

Probability (P)					
Life Expectancy—P1		**Failure Frequency—P2**		**Condition—P3**	
More than 10 years of expected life from today	1	No failure in the past 12 months	1	Brand New	1
Minimum 6 to 10 years of expected life based on the current condition and use	2	One failure in the past 12 months	2	Reliable (well maintained)	2
Minimum 3 to 6 years of expected life based on current condition and use	3	1–2 failures in the past 6–12 months	3	Average condition	3
Less than 3 years of expected life remaining	4	1–2 failures in the past 1–6 months	4	Poor condition—major changes or replacement anticipated	4
Urgent to replace.	5	More than two failures in the past month	5	Not maintainable or not operational, should be replaced	5

Table 4. Impact dimension KPIs (I1–I8).

IMPACT (I)							
Safety, Health—I1		**Environment *—I2**		**Alternative Option—I3**		**Quality—I4**	
No Safety, Health implications	1	No impact on environment	1	more than 1 alternative option available	1	No effect on the quality of the product	1
An accident/incident that may cause only minor injury	2	Minimal impact on Environment	2	Alternative option available with full capacity	2	Minimal Effect on the quality of the product, minimum deviations in output	2
An accident/incident that may cause moderate injury	3	Moderate impact on environment	3	Alternative with reduced capacity	3	Moderate Effect, output to be re-worked	3

Table 4. *Cont.*

IMPACT (I)							
An accident/incident that may cause serious injury	4	Major impact on Environment	4	Portable Alternative option with reduced capacity	4	High Effect and high deviations in the output that needs full rework	4
An accident/incident that may cause fatalities	5	Severe impact on Environment	5	Single Point of Failure (No alternative option is available)	5	Waste output	5
Good Manufacturing Practices GMP's—I5		**Production Time Loss—I6**		**Maintenance Costs—I7**		**Utilization—I8**	
No effect	1	Minimal (<1 h)	1	Minimal (less than $100)	1	Equipment Used rarely	1
Minor	2	Minor (1–3 h)	2	Minor ($100–$499)	2	Equipment is required up to 25% of the production time	2
Moderate	3	Average (3–8 h)	3	Moderate ($500–$2999)	3	Equipment is required 25–49% of the production time	3
Major	4	Major (one day)	4	Major ($3000–$6999)	4	Equipment is required 50–75% of the production time	4
Severe (Critical)	5	Severe (more than one day)	5	Severe ($7000 or more)	5	Equipment is completely needed during the production time	5

* Emission, dust and chemical impact on environment.

Table 5. Maintainability Complexity dimension KPIs (M1–M2).

Maintainability Complexity (MC)			
Ease of Diagnosis (M1)		**Ease of Resolution (M2)**	
Fault is instantly/automatically identified by sensors or diagnostic systems (No human effort required; issue is self-reported and categorized)	1	Fault is resolved instantly through reset, software patch, or simple part swap (less than 30 min maintenance time, no parts needed or already available)	1
Alarms or indicators make detection easy (issue is obvious to operators or through a quick visual check)	2	Simple physical repair or part replacement using standard tools (less than 2 hrs. effort with minimal planning)	2
Requires standard inspection tools and trained technician (moderate ambiguity and effort)	3	Moderate repair involving disassembly or scheduled downtime (may need 3-8 hours of maintenance and local spare parts)	3
Needs special tools or external experts (complex; diagnosis time adds significant delay	4	Complex repair involving special parts, tools, or safety protocols (downtime more than 1 day or requires manufacturer-level support)	4
Root cause is unknown or obscured (trial-and-error required; high misdiagnosis risk)	5	Restoration needs complete unit overhaul or replacement (critical downtime (multi-day), high cost, or limited serviceability)	5

To avoid conceptual overlap between dimensions, it is important to distinguish their scope. Although both I6 (Production Time Loss) and M2 (Ease of Resolution) involve downtime, they capture independent aspects: I6 reflects the consequence of downtime on production output, while M2 assesses the effort, time, and resources needed to resolve the failure.

Scoring was performed by an expert panel comprising representatives from Engineering, Quality Assurance, Operations, and Maintenance departments. Data sources included CMMS records, inspection logs, deviation reports, and equipment history. Consensus was reached via expert elicitation. To minimize bias in expert scoring, calibration sessions were conducted before the final assessment. Panel members reviewed example cases and discussed scoring interpretations until consensus was achieved, reducing variability between

raters. Discrepancies were resolved through structured cross-functional discussions, similar in principle to Delphi rounds, to ensure alignment across functions.

3.3. Aggregation Strategies

To synthesize the KPI scores into composite dimension scores, two aggregation approaches were tested: first, Multiplicative Aggregation that reflects classical RPN logic and emphasizes high-risk outliers. Second, Normalized Averaging that mitigates score skewness by smoothing extremes, offering a more balanced assessment. Both methods were applied across the asset set to analyze their effects on risk classification and clustering behavior.

3.4. Risk Stratification with Jenks Optimization Method

Rather than applying arbitrary RPN thresholds (e.g., >100), asset scores for each dimension (P, I, MC) were segmented using Jenks Natural Breaks Optimization. Jenks Natural Breaks Optimization was selected because it minimizes intra-class variance while maximizing inter-class variance, producing internally consistent and interpretable groupings. This interpretability is particularly valuable in GMP maintenance planning, where asset classifications must be transparent to engineering and quality personnel. In contrast, clustering methods such as k-means or hierarchical clustering may impose arbitrary partitions or require assumptions about cluster shape and number, which can reduce transparency for operational decision-making [23,24].

3.5. Study Context and Data Collection

The model was tested at a single GMP-certified pharmaceutical manufacturing facility. Data was collected from existing CMMS logs, historical maintenance records, and on-site expert assessments.

3.6. Framework Implementation Steps

The operationalization of the enhanced RPN model followed a structured eight-step process:

1. Asset Inventory and Data Collection: Assembled equipment metadata, CMMS history, and deviation reports.
2. KPI Scoring (P, I, MC): Applied expert scoring across 13 KPIs using the criteria in Tables 3–5.
3. Dimension Aggregation: Computed composite scores per dimension using both aggregation methods:

$$\textit{Probability Score} = \prod_{j=1}^{3} \mathrm{P}_j, \quad \textit{Impact Score} = \prod_{i=1}^{8} \mathrm{I}_i, \quad \textit{Maintability Score} = \mathrm{M}_1 \times \mathrm{M}_2$$

4. Jenks Clustering: Transformed continuous scores into ordinal tiers (1 = Low, 2 = Medium, 3 = High).
5. Enhanced RPN Calculation: Derived final score as: RPN = P × I × MC. This resulted in values ranging from 1 to 27.
6. Three-Dimensional Matrix Mapping: Assets were positioned within a 3 × 3 × 3 criticality matrix (Figure 2).
7. Maintenance Prioritization: Assets were categorized by RPN score:
   - Green Zone: Annual/on-the-fly preventive maintenance (PM);
   - Yellow Zone: Semi-annual PM;
   - Red Zone: Quarterly or CMMS-triggered PM.

8. To ensure reliability and reduce bias, cross-functional calibration sessions were conducted with scoring panels. However, because the framework was tested in a single pharmaceutical facility, its findings may not be directly generalizable to all contexts. While the structured KPI framework and statistical clustering methods are transferable by design, variations in organizational culture, regulatory emphasis, and asset mix may influence outcomes. Nonetheless, the framework is structured around GMP-driven risk principles and KPI definitions that are broadly applicable across pharmaceutical manufacturing. With appropriate adaptation, it could also be transferred to other regulated industries such as biotechnology or food processing, which face similar compliance and maintenance challenges. Future cross-site validation will therefore be valuable to confirm its robustness in diverse operational settings.

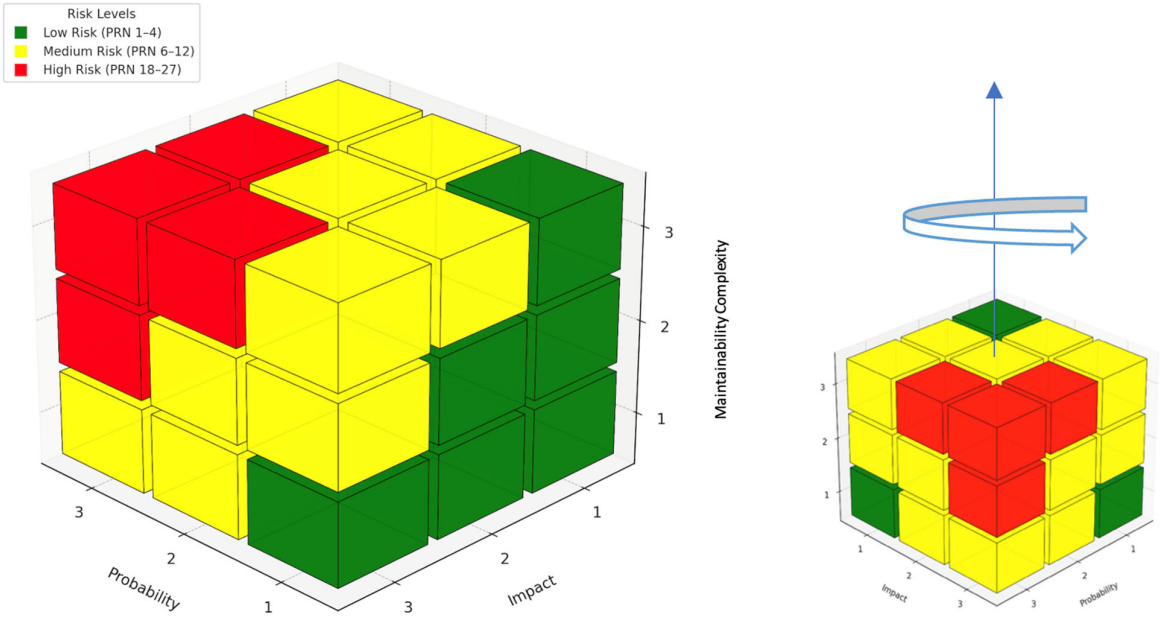


Figure 2. Three-dimensional Criticality Cube for Maintenance Stratification.

3.7. Tools and Deployment

All scoring, aggregation, and clustering were conducted using Microsoft Excel 365, Version 16.101.1, 2025 to ensure usability within standard CMMS platforms. The modular design of the framework facilitates reuse and scalability across other facilities and regulated industries.

4. Results and Discussion

This section presents the findings derived from applying the enhanced RPN framework to 185 utility assets within a GMP-compliant pharmaceutical facility. Following the structured eight-step methodology described earlier, results are discussed across four thematic areas: dimensional risk evaluation and comparative analysis of aggregation strategies, enhanced RPN computation and clustering, development of the 3D matrix-based maintenance plan, and interpretation of implications for pharmaceutical asset management.

4.1. Evaluation of Risk Dimensions and Clustering Accuracy

Each asset was evaluated across the three risk dimensions: P, I, and MC. KPI-based scores were aggregated using both normalized averaging (Table 6) and multiplicative (Table 7) approaches to understand how score distribution and cluster formation varied between methods. Jenks Natural Breaks Optimization was applied to each risk dimension to segment assets into low, medium, and high-risk categories.

Table 6. Jenks Natural Breaks Optimization; results are calculated based on average.

Optimal Break Points	Probability	P Count	%	Impact S	I Count	%	Maintainability	M Count	%
LOW RISK	Low (≤2.0)	49	26.49	Low (≤2.5)	54	29.19	Low (≤2.5)	55	29.73
MEDIUM RISK	Medium (>2.0 to ≤3.0)	94	50.81	Medium (>2.5 to ≤3.0)	25	13.51	Medium (>2.5 to ≤3.5)	104	56.22
HIGH RISK	High (>3.0 to 4.67)	42	22.70	High (>3.0 to 3.875)	106	57.30	High (>3.5 to 4.5)	26	14.05
Goodness of Variance Fit (GVF)	0.8484			0.914			0.945		
Data Range	1.33 to 4.67			1.75 to 3.875			1.5 to 4.5		
Mean	2.72			3.037			2.88		
Standard Deviation	0.730141136			0.506265528			0.66		

Table 7. Jenks Natural Breaks Optimization; results are calculated based on multiplication.

Optimal Break Points	Probability	Count	%	Impact S	Count	%	Maintainability	Count	%
LOW RISK	Low (≤16)	63	34.05	Low (≤5760)	80	43.24	Low (≤6)	55	29.73
MEDIUM RISK	Medium (>16 to ≤48)	117	63.24	Medium (>5760 to ≤17,280)	88	47.57	Medium (>6 to ≤12)	104	56.22
HIGH RISK	High (>48 to 100)	5	2.70	High (>17,280 to 43,200)	17	9.19	High (>12 to 20)	26	14.05
Goodness of Variance Fit (GVF)	0.8474			0.914			0.954		
Data Range	2 to 100			32 to 43,200			2 to 20		
Mean	22.1783783			9110.313514			8.724324324		
Standard Deviation	16.8861231			9218.506806			3.907678194		

The clustering performance was measured using the Goodness of Variance Fit (GVF), a statistical metric indicating how well a classification explains variance within the dataset. Table 8 illustrates that for all three dimensions, GVF exceeded 0.84, indicating strong within-group cohesion and between-group separation. This clearly shows that both methods are acceptable and robust. However, the MC dimension achieved the highest GVF in both aggregation approaches, particularly under multiplicative aggregation (GVF = 0.954), suggesting that MC scores were slightly more effective in delineating distinct levels of maintainability burden.

Table 8. GVF results for both averaging and multiplication approaches.

Risk Dimension	GVF (Averaging)	GVF (Multiplicative)
Probability	0.8484	0.8474
Impact	0.9140	0.9140
Maintainability Complexity	0.9450	0.9540

In addition to the tabular outputs presented in Tables 6 and 7, a graphical comparison was developed to contrast the normalized averaging and multiplicative aggregation methods across the three dimensions of P, I, and MC. As shown in Figure 3, the averaging method produced a more balanced distribution of assets across risk categories, whereas multiplication tended to concentrate assets in the medium-risk tier and minimize the number classified as high risk. This visualization highlights the interpretive differences between the two aggregation approaches and supports the selection of averaging as a more discriminative method for risk prioritization.

The averaging model produced a smoother distribution, with about half of the assets (50.8%) in the medium-risk category for Probability, and similar trends for MC and Impact. This method is effective in environments where moderate variability is expected and extremes should be down-weighted to avoid bias.

Conversely, the multiplicative model introduced more variance, sharpening distinctions across asset classes. For example, in the Probability dimension, only 2.7% of assets were classified as high-risk under multiplication, but those assets were clearly outliers in terms of score concentration. For MC, multiplicative scoring amplified differentiation

between medium and high-risk assets more effectively than averaging, providing a better fit for environments where compounding risk elements (e.g., high-impact + difficult resolution) must not be underestimated.

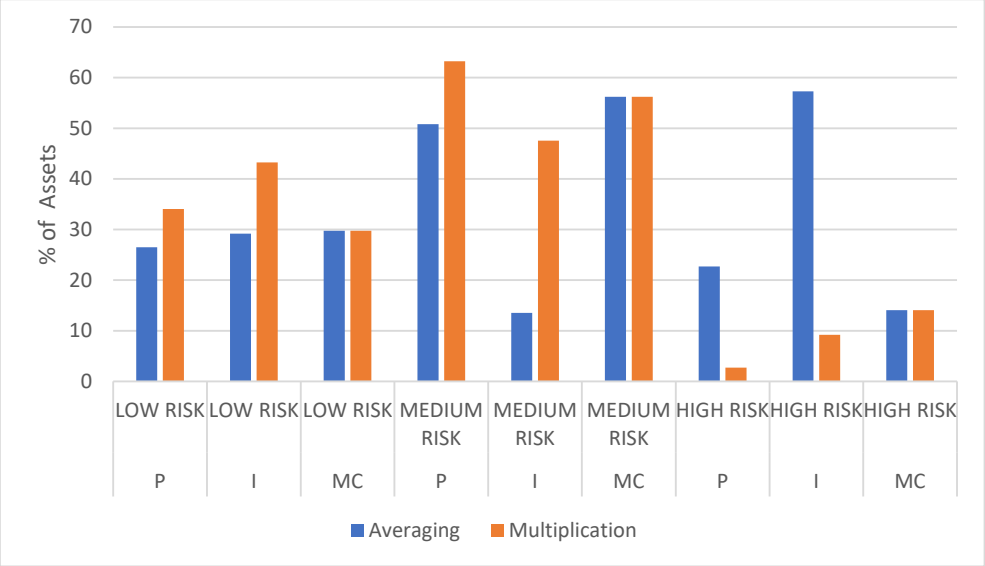


Figure 3. Comparative distribution of asset risk classification using normalized averaging (blue) and multiplicative aggregation (orange) across Probability (P), Impact (I), and Maintainability Complexity (MC) dimensions.

These differences reflect a fundamental modeling distinction: multiplicative aggregation emphasizes nonlinear relationships and interaction effects between factors. This is particularly important in pharmaceutical maintenance, where even moderate probability failures can become severe if maintainability is low and impact is high. The combined use of tables and graphical outputs improves interpretability and supports practical decision-making by making trade-offs between aggregation methods more explicit.

4.2. Final RPN Computation and Risk Stratification

After scoring and clustering each dimension, assets were assigned a discrete ordinal score: 1 (Low), 2 (Medium), or 3 (High). The final enhanced RPN score was then calculated as: Enhanced RPN = P × I × MC.

The resulting RPN values ranged from 1 to 27. Jenks Natural Breaks was once again applied to categorize overall risk scores into three tiers: Green (Low Risk), Yellow (Medium Risk), and Red (High Risk). The distribution is shown in Table 9 and Figure 4:

Table 9. Risk tiers for the RPN results.

Risk Tier	RPN Range	Asset Count	Percentage
Green	1–4	114	61.62%
Yellow	6–12	63	34.05%
Red	18–27	8	4.32%

The GVF for this final RPN clustering was 0.855, supporting the statistical validity of the classification system. The mean RPN score was 5.51, and the standard deviation was 4.25, indicating a positively skewed distribution. This enabled the strategic focusing of preventive resources on a small, well-defined subset of high-priority assets.

To assess the robustness of the enhanced RPN model, a basic sensitivity analysis was performed. Each dimension (P, I, and MC) was varied from 1 to 5 while holding the other

two constant at 2. Results showed that the RPN score is linearly sensitive to each input, with even a one-point change in any dimension leading to a proportional change in the overall RPN. This highlights the critical importance of consistent and accurate KPI scoring, particularly for MC, which can disproportionately influence maintenance prioritization in GMP contexts.

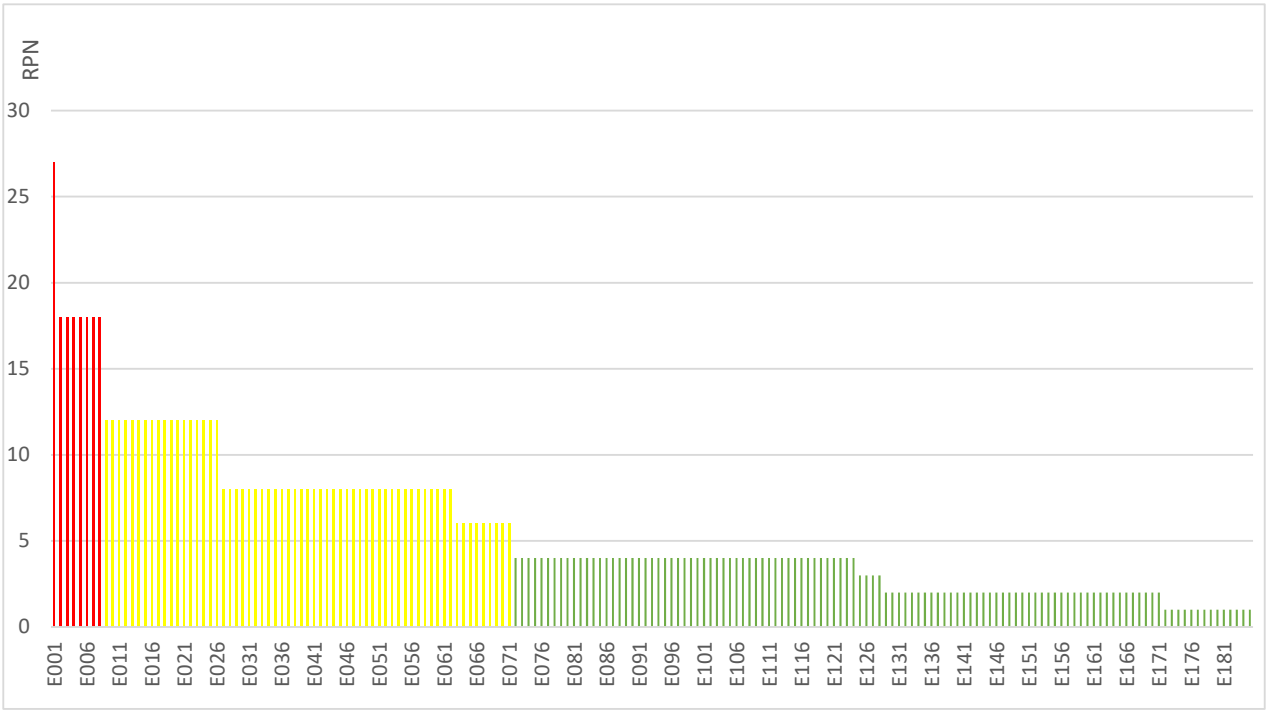


Figure 4. RPN values and risk tiers for the assets.

4.3. Mapping Risk to Action: 3D Matrix for Maintenance Strategy

To translate RPN insights into actionable planning, each asset was mapped into a $3 \times 3 \times 3$ matrix, where the axes represent discretized levels of Probability, Impact, and Maintainability Complexity. This results in 27 unique cells, each denoting a distinct risk profile.

Each zone was linked to a corresponding maintenance strategy, as shown in Table 10:

Table 10. Proposed Maintenance strategy.

Matrix–Cell Example	Interpretation	Recommended Maintenance Plan
[1, 1, 1] or [2, 1, 1]	Green zone (low across all)	Annual or On-the-Fly Preventive Checks
[2, 2, 2] or [1, 3, 2]	Yellow zone (medium or skewed)	Semi-Annual Scheduled Maintenance
[3, 3, 3] or [3, 2, 3]	Red zone (consistently high)	Quarterly or Condition-Based (CMMS Alerts)

This three-dimensional mapping introduces traceability between asset classification and maintenance scheduling, enhancing audit readiness and cross-functional transparency. Furthermore, it provides visual and logical coherence for planning teams, bridging the gap between risk analysis and operational execution. To ensure day-to-day practicality, the 3D matrix was implemented in Excel and directly mapped to existing CMMS fields. This allows maintenance teams to view and apply the risk stratification without additional data entry or software requirements. The matrix is intended primarily as a visual aid that enhances interpretability and scheduling traceability, rather than as an added layer of complexity.

4.4. Strategic Implications and Interpretation

The incorporation of MC as a core factor reshaped prioritization outcomes in meaningful ways. Assets with moderate failure likelihood and impact but high diagnostic or resolution difficulty were elevated to yellow or red tiers. This reclassification improves resource planning, especially in GMP settings where troubleshooting delays can cause compliance breaches or batch rejections.

The multiplicative model proved slightly effective in surfacing these latent risks, supporting its use in environments where failure interactions are nonlinear and interdependent. Meanwhile, the averaging method may remain useful in more stable systems or for organizations aiming to balance workloads across assets.

In a broader methodological context, it is important to compare the proposed enhanced RPN framework with alternatives such as fuzzy logic-based and weighted-FMECA approaches. Fuzzy and weighted methods offer improved mathematical sophistication and better handling of uncertainty; however, they often do not explicitly account for maintainability complexity. By contrast, our framework introduces Maintainability Complexity (MC) as a dedicated dimension, operationalized through Ease of Diagnosis and Ease of Resolution, thereby capturing diagnostic and resolution burdens that directly affect maintenance planning. The model therefore complements, rather than replaces, fuzzy or weighted approaches: it can be applied independently or in combination with them to strengthen both accuracy and usability in GMP-regulated environments.

Beyond methodological comparisons, the refined model also demonstrates several key operational strengths:

- Objectivity: The structured KPI system minimizes subjectivity in scoring.
- Auditability: Each score and final recommendation can be traced to defined criteria.
- Digital Compatibility: The method integrates easily with CMMS and Industry 4.0 platforms, allowing for future integration with predictive analytics.
- Practicality: The 3D matrix is implemented in Excel and directly compatible with CMMS, ensuring usability in day-to-day maintenance without adding procedural complexity.

This results-driven validation of the enhanced RPN framework demonstrates its utility in aligning maintenance planning with actual operational risk. Through the integration of structured scoring, empirical clustering, and 3D matrix mapping, the approach supports more defensible, compliant, and efficient maintenance decision-making in pharmaceutical contexts.

Although this study focused on utility assets, the framework is grounded in generic risk dimensions (P, I, and MC) and structured KPIs that are not asset-type specific. With appropriate adaptation of KPI definitions, the approach could be extended to production equipment or other asset categories, and future studies should explore this broader applicability.

While the enhanced RPN framework demonstrated promising results, its application was limited to a single GMP-certified pharmaceutical facility, which may constrain the generalizability of findings. Additionally, the KPI scoring process relied on expert judgment and manual data review, which, although structured, introduces subjectivity and limits scalability. Future work could explore automating the KPI evaluation using integrated CMMS data, sensor inputs, or AI-based diagnostics to improve consistency and reduce effort. Integration with real-time monitoring and predictive maintenance platforms would further enhance the model's applicability in Industry 4.0 environments and allow for continuous risk reassessment.

5. Conclusions

This study developed and validated an enhanced Risk-Based Maintenance (RBM) framework tailored to the operational and regulatory demands of GMP-regulated pharmaceutical environments. Building upon limitations in the traditional Risk Priority Number (RPN) model, the proposed framework introduces Maintainability Complexity (MC) as a third core dimension, alongside Probability (P) and Impact (I), to better capture the diagnostic and resolution burdens associated with equipment failures.

Through the integration of 13 structured Key Performance Indicators (KPIs) and the application of Jenks Natural Breaks Optimization Method for empirical clustering, the framework ensures risk stratification is both statistically grounded and operationally meaningful. Comparative testing of multiplicative and normalized aggregation strategies revealed that while both approaches yield valid prioritization, the multiplicative method offers stronger sensitivity to compounding risk factors, particularly important when maintenance delays carry high compliance or quality risks.

The use of a 3D matrix to guide preventive maintenance planning strengthens traceability, facilitates CMMS integration, and aligns asset scheduling with real-world risk conditions. These features support strategic resource allocation, regulatory compliance, and provide readiness for future digital transformation within Industry 4.0 environments. Although the current implementation was Excel-based, the framework is designed to be readily adaptable for integration with CMMS platforms and predictive analytics tools in future applications.

From a policy and managerial perspective, the model offers a defensible, data-driven basis for prioritizing capital investment in asset upgrades, optimizing maintenance budgets, and aligning organizational maintenance policies with operational risk realities, especially critical in compliance-intensive sectors like pharmaceuticals. Future research should assess inter-rater reliability metrics in multi-site applications to strengthen confidence in the robustness of the KPI scoring process. Moreover, validation across multiple facilities and industry sectors will be essential to demonstrate the transferability and broader applicability of the framework.

Author Contributions: Conceptualization, S.A.-H. and A.H.; methodology, S.A.-H. and A.H.; software, S.A.-H. and A.H.; validation, S.A.-H. and A.H.; writing—original draft preparation, S.A.-H.; writing—review and editing, S.A.-H. and AH; visualization, S.A.-H. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Data Availability Statement: The original contributions presented in this study are included in the article. Further inquiries can be directed to the corresponding author.

Conflicts of Interest: The authors declare no conflicts of interest.

Abbreviations

The following abbreviations are used in this manuscript:

AI	Artificial Intelligence
CMMS	Computerized Maintenance Management System
D	Detectability
ED	Ease of Diagnosis
ER	Ease of Resolution
GMP	Good Manufacturing Practices
GVF	Goodness of Variance Fit
HVAC	Heating, Ventilation, and Air Conditioning
I	Impact

KPI	Key Performance Indicator
MC	Maintainability Complexity
MTTR	Mean Time To Repair
P	Probability
PM	Preventive Maintenance
RBM	Risk-Based Maintenance
RPN	Risk Priority Number

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