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A Knowledge-Based Performance Management System Framework: Case Study in the Medical Device Manufacturing Sector

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ABSTRACT

The company operates within a highly regulated medical device environment where quality consistency, documentation accuracy, and supply reliability are critical to complying with ISO 13485 and MDR requirements. With more than 95% of raw materials sourced internationally, the primary operational challenge was the high rate of late supplier deliveries. Between 2020 and 2024, 53.83% of deliveries arrived after the agreed schedule, representing a total purchase value of USD 2,003,408.53. This condition disrupted production scheduling and weakened operational credibility. This study aimed to identify the root causes of procurement inefficiencies and to develop a Knowledge-Based Performance Management System (KBPMS) tailored to the company's operational context. A qualitative-dominant mixed-method approach was employed, incorporating semi-structured interviews, questionnaire surveys, and secondary data analysis from historical purchasing records, supplier delivery reports, and internal standard operating procedures (SOPs). The analytical process was conducted in three stages: (1) root cause analysis using the Ishikawa diagram, (2) development of the KBPMS framework, and (3) application of the Analytic Hierarchy Process (AHP) to evaluate and prioritize improvement criteria. The findings reveal that procurement inefficiencies were driven by multiple interrelated factors rather than isolated operational errors. The AHP results identified five key performance indicators—Emergency Purchase, Supplier On-Time Delivery (OTD), On-Time Task Completion, Non-Conformance Report (NCR), and ERP Master Data Accuracy—as the highest priorities for performance evaluation. These indicators form the core structure of the proposed KBPMS. This study contributes both academically and practically. Academically, it demonstrates the effectiveness of integrating root cause analysis with AHP-based prioritization within a knowledge-driven performance management framework. Practically, it provides the company with a structured and sustainable model to enhance procurement reliability, reinforce regulatory compliance, and support proactive, data-driven decision-making through phased implementation and digital integration.

KEYWORDS *medical device; procurement; root cause; KBPMS; AHP; Data governance*

INTRODUCTION

The medical device manufacturing industry operated in a highly regulated global landscape, where compliance was not optional but a prerequisite for market entry and sustained operations (Gupte, Nitave, & Gobburu, 2025; Wong & Tong, 2025). International frameworks such as ISO 13485:2016, EU Medical Device Regulation (MDR) 2017/745, and the ASEAN Medical Device Directive (AMDD) define strict requirements for quality management, supplier qualification, traceability, and documentation. These regulations were designed to safeguard patient safety, ensure product reliability, and maintain public trust in medical technologies (Daryanani, Maduekwe, Baird, & Ehrenfeld, 2025; Rimpi, Verma, Pinky, & Baldi, 2025).

In this environment, supply chain management was not only a matter of operational efficiency but also of regulatory compliance (Awuah-Gyawu, Abdul Muntaka, Owusu-Bio, & Otchere Fianko, 2025; Nweje & Taiwo, 2025). The procurement of raw materials had to adhere to rigorous supplier evaluation processes, risk assessments, and change control procedures. This makes the selection, monitoring, and management of suppliers a critical

success factor for medical manufacturers (Beltran-Salomon et al., 2025; Edalatpanah, Sıcakyüz, Nourkhah, & Pamucar, 2025).

This principle also applied directly to the medical accessories used for neurological diagnostic equipment (Al-Hassani, 2025; Hossain, Rahman, & Hossan, 2025). For devices such as Electroencephalography (EEG) and Electromyography (EMG), every component, from electrodes to cables, had to meet the highest quality standards, which were thoroughly monitored and enforced throughout the supply chain (Al-Ayyad, Owida, De Fazio, Al-Naami, & Visconti, 2023).

Market reports indicated a steady and significant growth trend in the global EEG and EMG market over the next decade, driven by factors such as the increasing prevalence of neurological disorders, advancements in neurodiagnostic technology, and the expansion of healthcare infrastructure in emerging economies (Alsharif & Isa, 2025; Mahalakshmi, Palanivelu, & Kirubakaran, 2025). According to Technavio, 2024, the EEG and EMG device market was expected to grow at a compound annual growth rate (CAGR) of 7.84% from 2024 to 2028, creating both opportunities and challenges for manufacturers in this sector. The global market trend for EEG and EMG devices was presented in Figure 1.

Figure 1. Global EEG and EMG Devices Market
Source: Adapted from Technavio

From Figure 1, it could be seen that the global market was forecasted to steadily increase, creating opportunities as well as challenges for manufacturers. While market expansion presented a favourable business outlook, it also increased the pressure on manufacturing organizations to meet higher production volumes without compromising quality or compliance. This required a resilient procurement strategy capable of ensuring continuous availability of critical materials. An analysis of company internal purchasing data in Figure I.2 showed that total raw material procurement had increased year-on-year, reflecting both the growth in production demand and the expansion of product offerings.

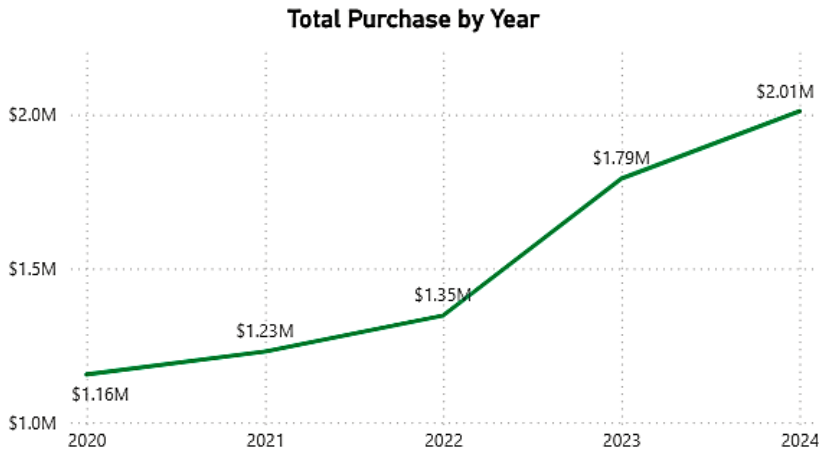

Figure 2. Total Purchase by Year
Source: Processed by researcher from PT TA internal purchasing data (2020-2024)

From Figure 2, in line with increasing of total purchase, it highlighted the importance of establishing a reliable procurement performance management system. However, this growth had been accompanied by a heightened reliance on overseas suppliers, with more than 95% of raw materials sourced internationally. The longest lead time was 220 days, and the average lead time was 53 days. This global dependency had led to recurring material shortages, emergency procurement, and production delays. In Table I.1, the company's dependency on international suppliers showed the proportion of raw materials sourced from different regions.

Table 1. Supplier's Region

Region	Percentage
America	**4,05%**
Asia	**68,97%**
Europe	**26,99%**

Source: Processed by researcher from PT TA internal supplier database (2024)

Referencing Table 1, the majority of the company's purchases—68.97%—were sourced from suppliers located in Asia, while European suppliers accounted for 26.99% and suppliers from the Americas represented the remaining 4.05%. The combination of stringent regulatory requirements, increasing market demand, and heavy reliance on overseas suppliers created a complex operational environment (Cherepovitsyn, Mekerova, & Nevolin, 2025; Otoko, 2025). In the absence of a robust and knowledge-driven performance management system, the procurement team operated largely in a reactive mode, addressing problems only after they occurred rather than implementing preventive controls.

To respond to the identified business challenges in procurement operations, supplier management, and the lack of a standardized performance measurement framework, this study addressed two primary research questions: (1) what key factors contribute to inefficiencies within the procurement team under the operational department, and (2) how can a

Knowledge-Based Performance Management System (KBPMS) be designed with relevant performance indicators and measurement criteria that align with the procurement function's strategic and operational objectives?

Based on these research questions, the study pursued two main objectives. First, to identify and analyze the core factors contributing to procurement inefficiencies, focusing on process gaps, resource constraints, and weaknesses in performance measurement (Komatina, Nestic, & Aleksic, 2019). Second, to design a tailored KBPMS framework incorporating appropriate performance indicators and evaluation criteria that ensure alignment with both strategic targets and day-to-day operational requirements (Ribeiro, 2025). By fulfilling these objectives, the study aimed to bridge the gap between theory and practice by providing PT TA with a structured performance management framework, while also contributing to academic discourse regarding KBPMS implementation in highly regulated industries (Hibban & Yudoko, 2025; Kaff, Wibisono, & Fatima, 2025).

This research was limited to the conceptual design of a KBPMS framework for PT TA, with the principal objective of establishing a structured performance management model aligned with the company's procurement and operational processes and supporting its corporate strategy. Primary data were to be collected through in-depth interviews with key internal stakeholders, including operational managers, PPIC managers, and quality assurance personnel. Secondary data were to be obtained from internal company documents such as supplier evaluation reports, procurement records, and performance metrics, as well as from relevant academic literature and regulatory guidelines applicable to the medical manufacturing sector (Pinto, 2020; Yu & Guo, 2024).

Several limitations were recognized in this study. External risks such as global supply chain disruptions, pandemics, international trade restrictions, and geopolitical instability were beyond the company's direct control yet could influence supplier performance. The KBPMS framework was specifically designed for PT TA and the medical manufacturing sector, potentially limiting its generalizability to other industries. The research did not include detailed financial performance analysis, capital budgeting evaluation, or comprehensive supply chain financial modeling. Furthermore, the study was restricted to the conceptual design phase of the KBPMS and did not encompass implementation, operational deployment, system monitoring, or predictive analytics functions. Data availability was confined to company-accessible internal systems and publicly available sources, excluding confidential supplier data. Finally, the research was conducted within an academic timeframe, which limited the possibility of extensive longitudinal analysis or assessment of seasonal procurement performance variations.

METHOD

The methodology used in this research was designed to answer the research questions and to achieve the stated objectives. A systematic approach was applied to ensure that the research process followed a logical sequence and provided reliable outcomes. This methodology was built on both theoretical foundations and practical considerations, allowing the study to identify the root causes of procurement inefficiencies and to propose a Knowledge-Based Performance Management System (KBPMS) tailored for the company.

Research Design

This research adopted a mixed-method design combining qualitative and quantitative approaches to address procurement inefficiencies and frequent supplier delivery delays. The qualitative stage employed root cause analysis through interviews with procurement and operations staff, focus group discussions, and document reviews to uncover systemic issues in processes, resource allocation, and coordination mechanisms. The quantitative stage applied the Analytical Hierarchy Process (AHP) to structure decision criteria, perform pairwise comparisons, and prioritize improvement strategies, enabling the design of a Knowledge-Based Performance Management System (KBPMS) framework aligned with strategic and operational goals. The research design, provided a clear roadmap from business overview and problem identification through data collection, analysis, framework development, and recommendations, ensuring consistency between research questions, objectives, and methods while bridging theoretical insights with practical solutions.

Data Collection Method

Data collection in this research involved both primary and secondary sources, using multiple methods to enhance validity and reliability.

1. Primary Data Sources
   a. Semi-structured interviews were conducted with procurement managers, operations planners, and quality assurance personnel to identify operational bottlenecks and gain insights into supplier performance challenges.
   b. Focus group discussions were carried out to validate and enrich the causes that had been identified in the Ishikawa diagram.
   c. Questionnaire surveys were distributed to key stakeholders to perform AHP pairwise comparisons for strategy prioritization.
2. Secondary Data Sources
   a. Historical purchase and supplier performance records were reviewed, including total purchase volumes, delivery timeliness, lead time adherence, and defect rates.
   b. Internal procurement SOPs and operational planning schedules were analyzed to provide additional context and support for the findings.

This combination of data sources ensured that root cause identification was comprehensive and that strategy prioritization was based on accurate and representative information.

Data Analysis Method

The data analysis process was divided into three stages, each corresponding to a specific analytical tool.

1. Root Cause Analysis using Ishikawa Diagram
   The Ishikawa (Fishbone) diagram was applied to categorize and visualize the causes of late supplier deliveries into main factors: Supplier, Logistics, Regulatory, Communication, Internal Processes, and Market. Causes that were identified through interviews and focus group discussions were mapped into the diagram to ensure a structured and complete problem diagnosis.
2. Framework Development using KBPMS
   The Knowledge-Based Performance Management System (KBPMS) was designed by integrating theoretical insights from performance measurement literature with the

operational realities of the company. Supplier performance indicators, compliance requirements, and strategic alignment principles were incorporated into a framework that could continuously monitor and manage procurement activities.

3. Prioritization Using AHP

   Criteria for improvement strategies were derived from the root cause analysis. AHP was applied to quantify the relative importance of each criterion through pairwise comparisons that were gathered from expert respondents. The method produced a ranked list of improvement strategies, provided clear decision-making guidance for implementation.

By combining these analytical tools, the research methodology ensured that findings were based on a systematic diagnosis of the problem, a theoretically grounded solution framework, and a quantitatively justified prioritization of actions.

RESULT AND DISCUSSION

SWOT-TOWS Analysis

The SWOT analysis conducted for PT TA provides a strategic perspective that complements the detailed operational findings derived from interviews and surveys. While interview results highlight micro-level process gaps and human factor issues, the SWOT framework elevates the discussion to an organizational and strategic dimension. This dual-layer analysis is essential in designing a Knowledge-Based Procurement Performance Measurement System (KBPMS), as performance measurement must be grounded in a clear understanding of both internal capabilities and external constraints.

The SWOT findings reveal that PT TA possesses several critical strengths, although these are often constrained by systemic weaknesses. Simultaneously, the company operates in an environment that offers opportunities for improvement—particularly through digital transformation and supplier development—yet is exposed to significant risks associated with demand volatility, regulatory complexity, and global supply chain instability.

From an internal standpoint, PT TA's strengths are rooted in its regulatory foundation, experienced personnel, and the availability of an ERP platform (Business Central). As a medical device manufacturer operating under ISO 13485 and MDR-related standards, the company maintains high levels of documentation control, traceability, and quality assurance. These structural capabilities provide a strong baseline for the development of a performance measurement system, as employees are already familiar with audit requirements and documentation discipline.

Furthermore, collaboration with the company's Netherlands headquarters provides access to international procurement best practices and supplier intelligence. Although system utilization remains suboptimal, the existence of Business Central presents a strategic asset capable of supporting performance dashboards, master data governance, workflow automation, and digital KPI integration, provided it is activated through a structured KBPMS roadmap.

Despite these strengths, PT TA exhibits substantial internal weaknesses that limit procurement reliability. These weaknesses primarily stem from human competency gaps, inconsistent operational methods, and underutilization of available systems. Interviews indicate that PPIC personnel possess limited forecasting proficiency, Engineering teams often

deliver incomplete specifications, and Purchasing experiences repetitive Purchase Requisition (PR) clarifications due to inconsistent data standardization. Manual Excel-based planning within PPIC contributes to data duplication and inconsistent planning outputs.

Inaccurate master data—such as erroneous lead times, outdated minimum order quantities (MOQs), and inconsistent item descriptions—generates cascading planning errors throughout the supply chain. In addition, weak KPI governance characterized by reactive rather than predictive metrics further reduces transparency and accountability. These cumulative weaknesses form the underlying drivers identified in the Ishikawa root cause analysis.

Externally, PT TA faces substantial opportunities. The global digitalization trend within manufacturing and supply chain management creates an environment conducive to adopting automated, knowledge-based systems. Advanced ERP modules, supplier scorecards, predictive analytics, and automated alert mechanisms can significantly improve procurement responsiveness and planning accuracy.

The growing emphasis on regulatory traceability within the medical device sector provides further justification for investing in performance measurement systems, as such tools enhance audit readiness and compliance integrity. Opportunities for supplier development—particularly with established international partners—enable the standardization of lead times, improvement of documentation quality, and reduction of non-conformance reports (NCRs). Additionally, benchmarking against global medtech suppliers and OEM manufacturers offers reference points for enhancing KPI maturity and process capability.

However, the external environment also presents material threats. One of the most critical risks is highly volatile customer demand, particularly from private-label clients who frequently adjust order volumes without long-term contractual stability. This volatility places operational pressure on PPIC and Purchasing, often triggering emergency procurement actions.

Extended and unstable lead times from international suppliers constitute another significant threat, especially when compounded by documentation delays. Global logistics disruptions, geopolitical instability, and raw material shortages further intensify supply uncertainty. Moreover, stringent regulatory requirements—such as MDR compliance, ISO 13485 audits, and technical documentation obligations—introduce administrative complexity and lengthen operational cycle times.

Collectively, these factors confirm that PT TA operates within a risk-intensive procurement landscape. Consequently, performance measurement must evolve from reactive tracking toward predictive, risk-based KPIs supported by a structured, knowledge-driven framework capable of anticipating disruption rather than merely responding to it.

Table 2. SWOT Analysis

Strengths	Weaknesses
1. Strong reputation in the medical device industry with high quality standards.	1. ERP data are inaccurate, processes rely on manual Excel files
2. Basic technologies are available (ERP, barcode), serving as a foundation for developing a knowledge-	2. Limited forecasting and data-analysis skills among staff.

based system.	
3. Practical experience of human resources in warehouse, PPIC, purchasing, and engineering is relatively strong.	3. Long approval process for procurement's workflow lead to delay.
4. Regulatory documentation and internal quality standard available.	4. KPIs lack alignment, predictiveness, and comprehensiveness.
5. Strong organizational commitment to quality and compliance.	5. Dependence on a single warehouse verifier and frequent incompleteness in technical specifications.
Opportunities	**Threats**
1. Digitalization in the medical industry provides opportunities to strengthen knowledge-based systems.	1. Customer demand instability and frequent forecast changes.
2. Increasing requirements for traceability and data integrity encourage performance system improvements.	2. Long, unstable lead times and delayed quality documents.
3. Advances in ERP and automation technologies enable improved data integration.	3. Strict medical regulations, periodic audits, and certification requirements extend procurement cycles.
4. Opportunities to strengthen collaboration with suppliers for performance improvement.	4. Global supply chain disruptions and shortages of critical materials.
5. Adoption of predictive methods can enhance operational stability.	5. Dependence on low-performing suppliers increases production risks.

Source: Compiled by researcher from interviews with PT TA key stakeholders (procurement managers, PPIC managers, operations planners, and quality assurance personnel) and focus group discussions conducted in 2024

The TOWS analysis synthesizes these internal and external factors into strategic directions. By combining strengths and opportunities, the SO strategy suggests that PT TA can leverage its regulatory culture and ERP system to accelerate digital transformation. This includes implementing automated workflows, dashboarding tools, and knowledge documentation systems that enhance traceability and process consistency.

The WO strategy emphasizes using digitalization and data-driven methods to address internal weaknesses, such as replacing manual spreadsheets with MPS-driven planning, developing supplier scorecards based on real performance data, and introducing KPI systems that reflect root causes and predictive insights.

The ST strategy proposes utilizing existing strengths—such as ISO compliance culture and cross-site procurement collaboration—to reduce the impact of external threats. For instance, using ERP-driven safety stock logic and supplier risk classification can help mitigate lead-time instability.

Finally, the WT strategy highlights the need to eliminate internal weaknesses to prevent external threats from escalating. This includes strengthening technical documentation quality to avoid delays from suppliers, improving master data to respond more effectively to logistic disruptions, and aligning cross-functional KPIs to ensure consistent reactions to demand volatility.

Table 3. TOWS Matrix

INTERNAL / EKSTERNAL	STRENGTHS	WEAKNESS
	1) A strong reputation in the medical device industry with high quality standards. **2)** The availability of basic technologies (ERP, barcode), serving as a foundation for developing a knowledge-based system. **3)** Strong practical experience among human resources in warehouse, PPIC, purchasing, and engineering functions. **4)** Availability of regulatory documentation and internal quality standards. **5)** The company's commitment to quality and industry compliance.	**1)** ERP data are inaccurate, processes rely on manual Excel-based work, and no supplier database is available. **2)** Limited forecasting and data-analysis skills among staff. **3)** Long approval process for procurement's workflow lead to delay. **4)** KPIs lack alignment, predictiveness, and comprehensiveness. **5)** Dependence on a single warehouse verifier and frequent incompleteness of technical specifications.
OPPORTUNITIES	(SO)	(WO)
1. The digitalization of the medical industry creates opportunities to strengthen its knowledge-based systems. 2. Increasing demand for traceability and data integrity are driving improvements in performance systems. 3. Developments in ERP and automation technologies support stronger data integration. 4. Opportunities to expand collaboration with suppliers to improve performance. 5. The company can adopt predictive methods to enhance operational stability.	SO1. Optimize the existing ERP system and barcode technology as a digitalization foundation for developing a Knowledge-Based Performance Measurement System (KBPMS). SO2. Leverage the company's strong reputation in the medical industry to promote the integration of traceability and data integrity across procurement and production workflows. SO3. Utilize the practical experience of human resources to adopt automation and cross-functional data integration within the ERP system, enabling more efficient performance monitoring processes. SO4. Use the company's commitment to quality and compliance to strengthen strategic collaboration with suppliers in the development of data-driven performance improvement. SO5. Integrate regulatory documentation and internal quality standards as foundational inputs for developing predictive models aimed at reducing operational uncertainties.	WO1. Transform the workflow using digital solution. This transition is expected to improve data reliability within the ERP system. WO2. Develop an auto update and integrate traceability features to improve the quality and completeness of the necessary information. WO3. Offer capacity-building programs for PPIC and purchasing teams focused on forecasting, statistical techniques, and data-driven decision-making. WO4. Adopt predictive methods (e.g., lead time estimation, material demand prediction) to address lengthy workflows and information uncertainties across functions. WO5. Formulate predictive KPIs based on historical data to support opportunities for digital performance monitoring and to meet the audit requirements of the medical industry.

THREATS	(ST)	(WT)
1. Customer demand instability and frequent forecast changes. 2. Long, unstable lead times and delayed quality documents. 3. Strict medical regulations, periodic audits, and certification requirements that extend the procurement cycle. 4. Global supply chain disruptions and shortages of critical materials. 5. Dependence on low-performing suppliers, which increases production risk.	ST1. Use the company's strong quality practices and established regulatory documents to reinforce the supplier assessment process, with particular attention to risks related to delays and the reliability of COA/COC submissions. ST2. Optimize barcode technology and the ERP system to improve the accuracy of material monitoring, enabling earlier detection of supply chain disruptions. ST3. Leverage the practical experience of human resources in daily operations to improve responsiveness to rapid forecast and customer demand changes. ST4. Rely on the company's strong reputation to establish long-term contracts with more reliable suppliers, thereby reducing dependence on low-performing vendors. ST5. Strengthen internal compliance based on medical standards to hasten the approval process for materials affected by strict regulations.	WT1. Implement standardized PR formats, engineering specifications, and approval flows to minimize the risk of material delays from suppliers and reduce dependence on documents that are frequently late. WT2. Establish supplier diversification based on risk and performance analysis to decrease reliance on low-performing suppliers. WT3. Develop predictive KPIs such as lead time deviation, supplier reliability trends, and planning accuracy to mitigate volatility in customer forecasts. WT4. Develop automatic reminders and dashboard alerts within the ERP system to address data inaccuracies and accelerate operational responses to global supply chain risks. WT5. Strengthen human resource capacity and increase the number of warehouse verifiers to reduce operational bottlenecks that exacerbate external threats such as material delays.

Source: Developed by researcher based on SWOT analysis results (Table 2) and strategic planning sessions with cross-functional teams at PT TA, 2024

The SWOT and TOWS analyses reinforce the central conclusion that PT TA requires an integrated, knowledge-based performance measurement system. Such a system must not only enhance internal process discipline but also prepare the organization to adapt to external pressures through strategic alignment, predictive measurement, and cross-functional integration. These strategic insights form the foundation for designing the KBPMS in the subsequent sections.

IV.2 KBPMS Design

The development of the Knowledge-Based Performance Management System (KBPMS) for PT TA begins with a systematic and structured approach that ensures alignment between foundational organizational principles, environmental realities, strategic objectives, performance variables, and continuous improvement mechanisms.

Following the theoretical framework, the KBPMS design starts with the establishment of a solid foundation (Stage 0), proceeds to analyzing the contextual background of the business environment (Stage 1), continues by formulating the performance system components (Stage 2), and culminates in the implementation and refinement stages (Stage 3 and Stage 4).

IV.2.1 Stage 0 — Foundation

Stage 0 establishes the philosophical and cultural foundation required for an effective performance management system. In PT TA, the foundation is particularly important because the analysis revealed deep-rooted issues related to communication norms, competency gaps, documentation discipline, and cross-functional alignment. These elements must be addressed before the performance measurement system can operate effectively.

1. **Partnership**

   The partnership element emphasizes the importance of collaborative relationships among internal functions and external stakeholders. At PT TA, it showed that existing interdepartmental relationships lack strategic alignment and are predominantly transactional. For example, PPIC often relies on incomplete historical data and uses manual spreadsheets, resulting in inaccurate forecasts that heavily impact Purchasing.

   As stated by the PPIC Manager during interviews, the department often works "based on assumptions," signaling a lack of structured coordination.

   From the Purchasing perspective, incomplete PRs and late communication from Engineering significantly affect procurement cycle time. This lack of upstream partnership creates a chain of reactive responses down the process. Meanwhile, the Netherlands Purchasing representative highlighted that misalignment between Indonesian operations and the global planning approach results in recurring supplier misunderstandings, stating that "if the data in Business Central is wrong, then everything downstream will be wrong." Strengthening partnership requires establishing shared objectives, synchronized data flows, and joint problem-solving mechanisms.

2. **Empowerment**

   Empowerment in KBPMS refers to enabling individuals with adequate knowledge, competencies, resources, and authority to perform their roles effectively. PT TA's interviews revealed that staff across PPIC, Engineering, Warehouse, and Purchasing lack sufficient training in critical areas such as forecasting methodology, ERP operations, data maintenance, documentation standards, and supplier communication.

   Many PPIC employees learned their tasks informally, while Engineering staff admitted to providing technical specifications reactively rather than proactively. The Warehouse verification process is constrained by manpower limitations, placing excessive burden on one individual. These conditions demonstrate that employees at PT TA are not fully empowered to support a performance-driven environment. Empowerment within KBPMS will require structured competency development programs, ERP utilization training, standardized workflows, and sufficient allocation of resources, including staffing and digital tools.

3. **Integrated Improvement**

   Integrated improvement refers to the collective and continuous effort to improve processes across departments. At PT TA, improvement initiatives have historically been isolated within individual departments rather than coordinated enterprise-wide. The dependency on Excel-based processes in PPIC, the inconsistent technical documentation in Engineering, and the fragmented KPI landscape illustrate the absence of a unified improvement process. Interviews show that when problems arise—such as supplier

delays—the immediate reaction is often departmental defense rather than cross-functional collaboration.

Integration must therefore be embedded through shared KPI ownership, standardized documentation repositories, and coordinated process improvement cycles that link PPIC, Engineering, Purchasing, Warehouse, and QA into a single improvement framework.

4. **Independence**

Independence refers to the ability of the performance management system to operate objectively, free from individual biases, knowledge silos, or undocumented practices. PT TA currently relies heavily on personal memory, individual Excel files, and verbal communication. Warehouse verification is dependent on a single employee; PPIC knowledge is concentrated among a few staff members; Engineering specification updates are not systematically documented; Purchasing tracks supplier performance manually.

These dependencies introduce significant operational risk. To achieve independence, PT TA must ensure that knowledge is institutionalized, processes are documented, data is stored systematically, and workflows do not rely on individual discretion. The KBPMS will address this by establishing centralized documentation repositories, enforcing ERP-driven workflows, and promoting data-driven decision-making.

IV.2.2 Stage 1 — Basic Information

Stage 1 provides an objective understanding of PT TA's internal and external environments. The reference thesis stresses that performance indicators must reflect the strategic context in which the organization operates. Therefore, PT TA's business environment was analyzed using PESTEL for external factors and VRIO for internal capabilities.

1. **External Environment Analysis (PESTEL)**

Political

PT TA is affected by international trade regulations and import policies because many raw materials and medical accessories are imported from Europe or Asia. Customs clearance requirements, import restrictions on medical components, and government-issued certifications such as COA/COC add administrative complexity. Moreover, regulatory audits from Ministry of Health influence procurement timing and documentation accuracy.

Economic

Currency fluctuations, global inflation, and logistics disruptions impact procurement cost and lead time. Interviews with Purchasing revealed that certain items require up to 10 months lead time due to international shipping constraints and unpredictable freight schedules. Economic instability can also affect suppliers' ability to meet volume commitments.

Social

As a medical device manufacturer, PT TA operates in a sector where safety, reliability, and quality are social expectations. Customer demand for private-label products changes rapidly, creating pressure on internal planning processes. Consumer awareness of medical device standards also shapes production and procurement requirements.

Technological

PT TA uses Microsoft Dynamics Business Central as its ERP system. However, interviews confirmed that the system is underutilized: incorrect master data, missing reminders, and limited use of the MPS module restrict technological benefits. The Warehouse employs barcode systems, but these are not fully integrated. Technology presents opportunities for automation and predictive planning if utilized properly.

Environmental

Sustainable practices in supply chains are increasingly important. Although not the main challenge for PT TA, global environmental disruptions (e.g., natural disasters, supply chain interruptions) indirectly affect lead times. Additionally, compliance with environmental standards in manufacturing is required for international markets.

Legal

PT TA operates under ISO 13485, requiring strict documentation, supplier qualification, traceability, and risk management. MDR regulations impose strict requirements on material traceability and technical documentation. Supplier delays in providing COA or COC can delay material acceptance and production.

2. **Internal Environment Analysis (VRIO)**

According to the Resource-Based View (RBV), organizational performance is largely influenced by the firm's ability to deploy valuable, rare, inimitable, and organized (VRIO) resources (Barney, 1991; Barney, Ketchen, & Wright, 2021). Assessing PT TA's tangible and intangible resources is therefore essential to ensure the designed KPIs accurately reflect the firm's real capabilities and constraints.

Tangible Resources

PT TA possesses modern production equipment, a functioning ERP system, barcode capabilities, and a skilled technical team. However, resource utilization is suboptimal due to inconsistent processes and underdeveloped competencies.

Table 4. Tangible Resources Analysis

Category	Description	V	R	I	O	VRIO Evaluation
Production Facilities & Equipment	ISO 13485–compliant assembly lines, testing instruments, measuring tools for EEG/EMG/IONM accessories	Yes	No	No	Yes	Common industry capability
ERP System (Microsoft Dynamics BC)	Underutilized; inaccurate master data; MPS not used; no reminder automation	Yes	No	No	No	Not fully leveraged
Warehouse Barcode System	Barcode available but not fully integrated; manual verification persists	Yes	No	No	No	Limited operational impact
Material Handling Resources	Limited manpower (1 verifier), basic handling tools, insufficient storage optimization	Yes	No	No	No	Constrained and imitable
Financial Resources	Stable funding from HQ NL; emergency purchases increase costs	Yes	No	No	Yes	Valuable but unstable

Source: Compiled by researcher based on Resource-Based View (RBV) framework (Barney, 1991) and internal assessment of PT TA resources through interviews and document reviews, 2024

Intangible Resources

The company's intangible resources include cross-site support from the Netherlands, regulatory expertise, and global supplier networks. However, internal knowledge is poorly documented and heavily dependent on individual employees. This weakens the sustainability of operations and increases risk.

Table 5. Intangible Resources Analysis

Category	Description	V	R	I	O	VRIO Evaluation
Human Capital	PPIC limited forecasting knowledge; Purchasing overloaded; Engineering reactive; Warehouse understaffed	Yes	No	No	No	Weak organizational capability
Knowledge & Documentation Quality	No central repository; missing NCR history; inconsistent drawings; scattered Excel files	Yes	Yes	No	No	Poorly documented knowledge
Organizational Culture	Predominantly reactive; ad hoc communication; limited proactive planning	No	No	No	No	Weak; not valuable in current form
Supplier Relationship Quality	Long lead times, high dependence on single-source suppliers	Yes	Yes	No	No	Strategic but less organized
Regulatory & Compliance Capability	Strong ISO 13485 & MDR compliance; experienced QA team	Yes	Yes	Yes	Yes	Sustain competitive advantage

Source: Compiled by researcher based on Resource-Based View (RBV) framework (Barney, 1991) and internal assessment of PT TA intangible resources through interviews and focus group discussions, 2024

3. SWOT–TOWS Integration

The SWOT and TOWS analyses reveal that while PT TA has strong regulatory foundations, system capabilities, and access to global knowledge, its weaknesses—such as poor master data accuracy, manual processes, and fragmented KPIs—amplify external threats like demand volatility and long supplier lead times. Opportunities for digitalization, supplier development, and ERP optimization can be leveraged to overcome these weaknesses.

CONCLUSION

The research concludes that procurement performance issues at PT TA arise from an interconnected combination of systemic, process-related, and behavioural factors spanning multiple functional areas. Root cause analysis demonstrates that limited human competency—particularly within PPIC and Purchasing—combined with incomplete documentation, reactive communication patterns, and underutilization of ERP capabilities significantly contribute to procurement inefficiencies. In addition, material and supplier-related constraints, including long international lead times, single-source dependency, and the specificity of medical-grade components, intensify emergency purchases and delivery instability. These findings confirm that procurement inefficiencies do not originate from isolated operational errors, but rather from structural misalignment across people, processes, systems, suppliers, and regulatory demands.

The second major conclusion highlights that the development of a Knowledge-Based Performance Management System (KBPMS) offers a structured and systematic solution to address these interrelated challenges. Through the AHP prioritization process, five key performance indicators—Emergency Purchase (%), Supplier OTD (%), On-time Task Completion (%), NCR (%), and ERP Master Data Accuracy (%)—were identified as the most critical metrics directly linked to the root causes uncovered in the analysis. These KPIs serve as measurable control points that transform abstract issues into actionable performance levers.

The KBPMS framework clarifies the causal relationships between resource capabilities, internal processes, and resulting business outcomes. It enables Procurement and related functions to measure, evaluate, diagnose, and continuously improve performance through a structured and knowledge-driven mechanism. Through the implementation of KBPMS Stages 3 and 4, PT TA is expected to establish a performance management system that is cross-functionally integrated, strategically aligned, and capable of sustaining long-term operational excellence under ISO 13485 and MDR requirements.

In summary, the integration of root-cause analysis with a structured KBPMS framework significantly enhances procurement effectiveness, strengthens cross-functional coordination, improves supplier reliability, and reinforces regulatory compliance within the medical device industry context. The proposed KBPMS provides PT TA with a sustainable foundation for long-term operational stability, proactive risk management, and continuous improvement.

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