

## Strategic Model for Strengthening National Medical Device Industry Self-Sufficiency: A Mixed Methods Approach Based on Performance Indicators and Pentahelix Collaboration

Mario Apriliansyah<sup>1\*</sup>, Iha Haryani Hatta<sup>1</sup>, Widarto Rachbini<sup>2</sup>

<sup>1</sup>Doctoral Program in Economics, Universitas Pancasila, Jakarta, Indonesia

<sup>2</sup>Faculty of Economics and Business, Universitas Pancasila, Jakarta, Indonesia

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**Abstract:** The self-sufficiency of the medical device industry is a fundamental pillar in strengthening national health resilience, particularly in the post-COVID-19 context. However, structural challenges—such as fragmented cross-sector policies, import dependency, and weak inter-actor collaboration—remain key obstacles. This study proposes a strategic roadmap model to accelerate industrial self-reliance through a sequential exploratory mixed methods approach, beginning with qualitative exploration followed by quantitative analysis. Qualitative data were collected through 24 Focus Group Discussions (FGDs) involving pentahelix actors (academia, industry, government, community, and media) between 2021 and 2023, reinforced by the 2021 National Medical Device Industry Survey covering 148 firms from a population of 487. Structural validation was performed using a purposive sample of 32 key stakeholders, including representatives from ministries, industry associations, academia, and policymakers. Thematic analysis and grounded theory were used to extract qualitative insights. Meanwhile, quantitative data from the stakeholder survey were analyzed using Partial Least Squares - Structural Equation Modeling (PLS-SEM) with SmartPLS 3.2.6. The study identified six strategic dimensions that significantly influence industrial self-sufficiency: (1) regulatory and policy strengthening, (2) ecosystem visibility and transparency, (3) customer-oriented focus, (4) pentahelix collaboration, (5) supply chain agility, and (6) sustainability. The SEM model confirmed the statistical significance of these dimensions, with sustainability emerging as the most dominant predictor. Qualitative findings further emphasize the importance of cross-sector policy alignment, integration of research into production processes, and the provision of innovation-based local incentives.

**Keywords:** Medical Device Industry Self-Sufficiency, Mixed Methods, Strategic Roadmap, Pentahelix Collaboration, Performance Indicators, Health System Resilience, Structural Equation Modeling.

### 1. Introduction

National self-sufficiency in the medical device sector has emerged as a strategic priority in achieving health sovereignty and industrial resilience. The COVID-19 pandemic illuminated Indonesia's critical dependence on imported medical technologies, which impeded its timely and adequate public health response (WHO, 2021; Simola, 2022). In this context, enhancing domestic capabilities in medical device manufacturing is not merely an economic imperative but also a public health necessity (OECD, 2021; Karmaker & Ahmed, 2020).

Despite policy momentum, structural challenges persist—ranging from fragmented regulation and low visibility of innovation to supply chain vulnerabilities and weak cross-sector collaboration. Existing frameworks often fail to integrate the complexity of stakeholder roles and the dynamic requirements of the health innovation ecosystem (Etzkowitz & Leydesdorff, 2000). This study addresses this gap by constructing a validated strategic model based on performance indicators derived from Penta-helix collaboration and grounded in resilience theory.

### 2. Methods

#### 2.1 Research Design

This study adopts a sequential exploratory mixed methods design, combining the inductive richness of qualitative inquiry with the generalizability of quantitative analysis to formulate a robust strategic model for strengthening national medical device industry self-sufficiency. The research design is anchored in four foundational theoretical frameworks:

- a. Grounded Theory (Strauss & Corbin, 1990), is employed as the methodological basis for the qualitative phase to inductively construct conceptual categories from stakeholder narratives. This study adopts a Grounded Theory approach to construct a conceptual model of national medical device industry self-sufficiency based on six strategic determinants: regulation, visibility, customer focus, penta-helix collaboration, supply chain agility, and sustainability. Data were derived from 24 Focus Group Discussions (FGDs) conducted between 2021–2023, involving key stakeholders from ministries, industry, academia, and civil society. To enhance validity, findings were triangulated with open-ended responses from 148 industry actors. The coding process followed three systematic stages. Open coding identified 54 initial codes, which were grouped into 18 substantive categories. Axial coding mapped causal relationships among categories, forming six thematic dimensions such as Regulatory Orchestration and Customer-Centric Nationalism. Selective coding then synthesized these into a core category: Systemic Integration for Medical Device Industry Self-Sufficiency. The resulting model—MS-KIAKN—emphasizes that industry self-sufficiency is not isolated but emerges from the synergistic interaction of institutional, informational, and operational capacities. This model contributes theoretically to industrial resilience literature and offers practical insights for evidence-based policymaking in health industry development. The model is further strengthened through integration with three theoretical frameworks: Pharmaceutical Resilience Theory (Karmaker, 2020), emphasizing supply chain and institutional robustness; the Malcolm Baldrige Framework, linking strategic performance and sustainability; and the Penta-Helix Model, highlighting cross-sector collaboration. This interdisciplinary synthesis ensures the model's contextual relevance, theoretical depth, and applicability for evidence-based policy, institutional reform, and industrial transformation.
- b. Pharmaceutical Resilience Theory (Karmaker & Ahmed, 2020), which informs the quantitative phase by assessing the sector's capacity for adaptability, redundancy, and agility in response to systemic disruptions;
- c. Malcolm Baldrige Performance Excellence Framework (BPEF), which serves as an evaluative tool for organizational performance, strategic governance, and quality management within health industry systems;
- d. Pentahelix Collaboration Theory (Carayannis & Campbell, 2009), which conceptualizes multi-actor governance by integrating five key stakeholders—government, academia, industry, media, and civil society—into a co-creation framework for innovation ecosystems.

The study was executed in three distinct phases:

1. Qualitative Exploration Phase (2021–2023): Conducted through 24 focus group discussions (FGDs) involving informants from five sectors to identify key strategic constructs based on experiential narratives and thematic patterns.
2. Quantitative Analysis Phase: Constructs from the qualitative phase were operationalized into measurable indicators and validated through expert surveys (n=32). Structural Equation Modeling (PLS-SEM) was applied to examine inter-variable relationships and model fit.
3. Integration and Strategy Formulation Phase: Findings from both phases were synthesized to formulate a strategic roadmap of performance indicators and policy recommendations to support the autonomy of Indonesia's medical device industry.

This integrative and theory-driven research design enables both contextual depth and statistical validation, providing a rigorous and actionable framework for national industrial transformation in the health technology sector.

## 2.2 Theoretical Framework

Four foundational theories were integrated:

- Pharmaceutical Resilience Theory (Karmaker & Ahmed, 2020): Emphasizing agility and redundancy in supply systems.
- Malcolm Baldrige Framework (Baldrige Program, 2021): Strategic governance and customer-centric performance.
- Pentahelix Collaboration Model (Carayannis & Campbell, 2009): Multi-stakeholder co-creation for innovation ecosystems.
- Grounded Theory (Strauss & Corbin, 1990): Empirical construct development through iterative coding.

**2.3 Operationalization**

Dependent Variable:

- National Medical Device Industry Self-Sufficiency measured by:
- Share of local products in procurement
- TKDN compliance rates
- Proportion of devices with >25% domestic content

Independent Variables and Indicators:

1. Regulation & Policy: Clarity, consistency, and policy responsiveness
2. Visibility: Availability of innovation data, public exposure
3. Customer Focus: Responsiveness to health personnel needs
4. Pentahelix Collaboration: Data sharing, co-financing, joint innovation
5. Supply Chain Agility: Local input sourcing, responsiveness
6. Sustainability: ESG compliance, risk mitigation, long-term investment access

**2.4 Sampling and Analysis**

- Qualitative Data: Thematic coding (open, axial, selective) using stakeholder narratives
- Quantitative Data: This study adopted an open population approach, employing theoretical sampling and the principle of information power (Malterud et al., 2016) instead of conventional probabilistic sampling techniques. A total of 32 experts were selected based on their active involvement in the innovation and health ecosystems. Quantitative analysis was conducted using Partial Least Squares Structural Equation Modeling (PLS-SEM). Following Hair et al. (2019), the sample size was considered adequate due to the model’s simplified constructs and validated indicators. Measurement model assessment included Average Variance Extracted (AVE), Composite Reliability (CR), and Heterotrait-Monotrait Ratio (HTMT), with path significance tested through bootstrapping with 5,000 resamples ( $p < 0.05$ ).

**Table 1. Demographic Distribution of Respondents by Institutional Background**

Institution	n
Academics	11
Regulators/Government	10
Associations	5
Business/Industry	6
<b>Total</b>	<b>32</b>

Source: Processed by the author, 2025

**3. Results**

3.1 Strategic Constructs Identified

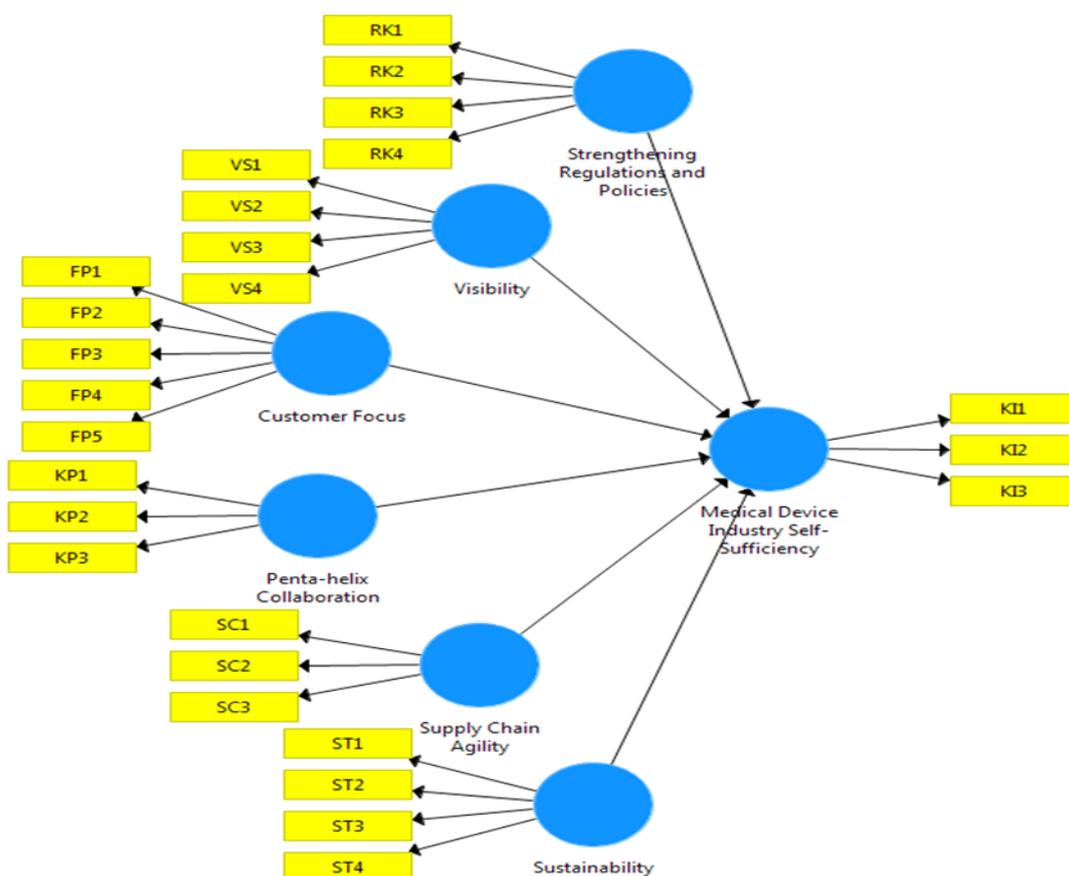
Six dimensions were inductively derived:

- Regulation & Policy: Centralized regulatory orchestration by the MoH, need for harmonized fiscal and certification instruments.
- Visibility: Lack of integrated data systems; low public recognition of local innovations.
- Customer Focus: Import bias among users; insufficient clinician involvement in device development.
- Pentahelix Collaboration: Fragmented partnerships; absence of integrated innovation financing.
- Supply Chain Agility: Limited domestic material base and adaptive manufacturing.
- Sustainability: The most significant driver encompassing ESG alignment, long-term financing, and circular economy practices.

### 3.2 Model Validation

This study employed a two-stage analytical approach using Smart PLS 3.2.6, consisting of outer model (measurement) and inner model (structural) evaluations. Construct validity was assessed via indicator loading factors, with acceptable thresholds above 0.5 or 0.7 depending on the analytical context. Reliability was confirmed using Cronbach’s Alpha and Composite Reliability to ensure internal consistency among indicators representing each latent variable.

Figure 1. Path Diagram of the Full Model



Source: Adapted from research findings, 2025

The SEM analysis confirmed all six constructs as significant predictors of self-sufficiency. The overall model yielded  $R^2 = 0.647$ , indicating substantial explanatory power. Sustainability had the highest effect ( $\beta = 0.464$ ,  $f^2 = 0.320$ ), followed by Penta-helix Collaboration ( $\beta = 0.393$ ) and Regulation & Policy ( $\beta = 0.372$ ). The research model consisted of 22 indicators and 7 latent constructs: Regulatory and Policy Strengthening (3 indicators), Visibility (4 indicators), Customer Focus (2 indicators), Penta-helix Collaboration (3 indicators), Supply Chain Agility (3 indicators), Sustainability (4 indicators), and Medical Device Industry Independence (3 indicators).

Table 2. Outer Loading Statistics

	Indikator		Loading Factor	Keterangan
Strengthening Regulation and Policies	RK1	Governance System	0,783	Valid
	RK2	Governance System	0,872	Valid
	RK3	Performance Evaluation	0,859	Valid
	RK4	Legal & Regulatory Compliance	0,603	Not Yet Valid
Visibility	VS1	Management Support	0,878	Valid
	VS2	Information Sharing	0,738	Valid
	VS3	Enviromental Uncertainty	0,903	Valid
	VS4	Operational Disruption	0,924	Valid
Customer Focus	FP1	Customer Expectation	0,724	Valid
	FP2	Customer Expectation	0,744	Valid
	FP3	Customer Engagement	0,724	Valid
	FP4	Customer Engagement	0,737	Valid
	FP5	Customer Engagement	0,839	Valid
Penta-helix Collaboration	KP1	Cross-Sector Coordination	0,907	Valid
	KP2	Data Integration & Access Convenience	0,889	Valid
	KP3	Innovation Ecosystem	0,678	Not Yet Valid
Supply Chain Agility	SC1	Availability of Local Raw Materials	0,909	Valid
	SC2	Supply Chain Speed	0,937	Valid
	SC3	Supply Chain Flexibility	0,877	Valid
Sustainability	ST1	Supply Chain Risk	0,845	Valid
	ST2	Product Complexity	0,683	Belum Valid
	ST3	Product Quality	0,906	Valid
	ST4	Environmental Uncertainty	0,447	Belum Valid
Medical Device Industry	KI1	Absorption of Local Products in Government Market	0,818	Valid
	KI2	Local Product with TKDN Certification	0,920	Valid
Self-Sufficiency	KI3	TKDN above 25 %	0,745	Valid

Source: Processed from research data (2025)

Convergent validity was assessed using the Average Variance Extracted (AVE) method, following the guidelines of Hair et al. (2014), which allow indicators with outer loadings between 0.40–0.70 to be retained if the construct’s AVE exceeds 0.50 and the indicators are theoretically justified. In this study, all constructs achieved AVE values above 0.50, confirming the convergent validity of all indicators included in the model.

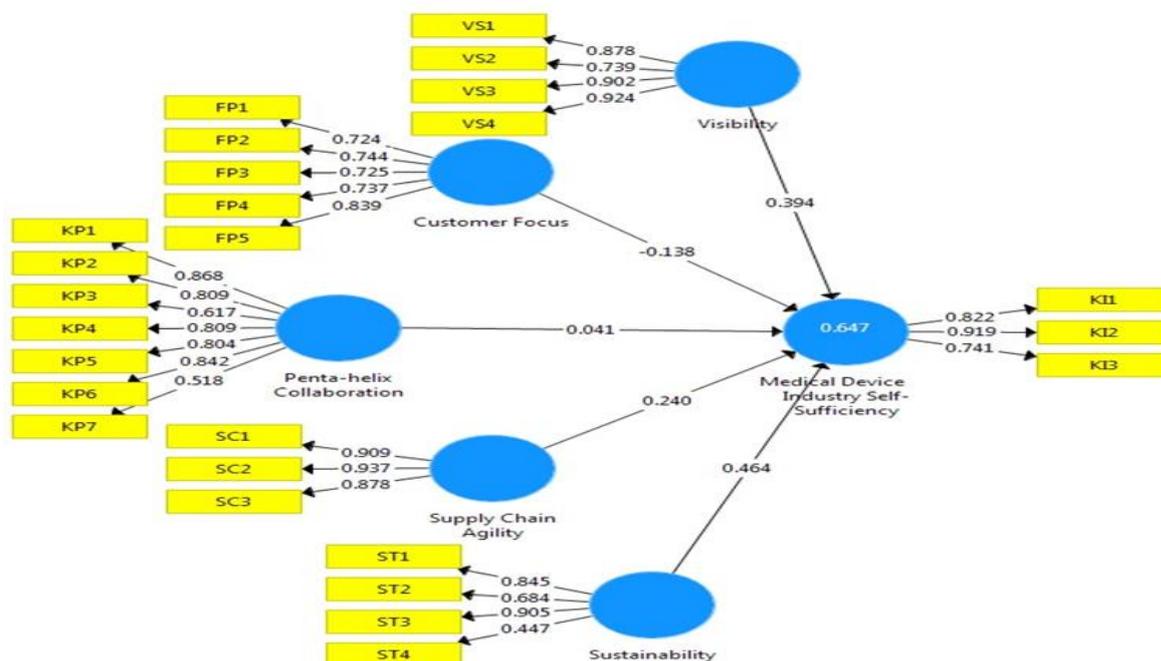
Discriminant validity was assessed using the cross-loading criterion, which requires that each indicator's correlation with its associated latent construct be higher than its correlations with other constructs. The analysis showed that all indicators loaded more strongly on their respective constructs compared to others, indicating that each latent variable is better predicted by its indicators. Therefore, the model satisfies the requirements for discriminant validity.

Composite reliability was assessed using Cronbach's Alpha, given the similarity in their interpretative criteria. A Cronbach's Alpha value of  $\geq 0.70$  is generally considered the threshold for acceptable internal consistency. In this study, all constructs, including team cohesion, demonstrated Cronbach's Alpha and Composite Reliability values exceeding 0.70. These results confirm that the constructs exhibit strong internal consistency and can be considered reliable for further structural analysis.

The discriminant validity test revealed that the square root of the AVE for the construct Regulatory and Policy Strengthening was lower than its correlation with Pentahelix Collaboration, indicating a violation of the Fornell-Larcker criterion (Fornell & Larcker, 1981). Additionally, the HTMT value of 0.961 further confirmed a lack of discriminant validity between the two constructs (Henseler, Ringle, & Sarstedt, 2015). Despite all indicators being convergent valid, these findings suggested that both constructs were empirically indistinguishable.

To address this issue, and in accordance with the principle of parsimony and the conceptual framework that views regulation as a catalyst for cross-sector collaboration (Crosby & Bryson, 2010), the constructs were merged into a unified variable titled Integrated Pentahelix Collaboration with Regulatory Support. The merged construct was subsequently re-evaluated for convergent validity and reliability using combined indicators, with results confirming its suitability for structural modeling.

Figure 2. Final Structural Model Path Diagram



Source: Processed by the researcher, 2025

Description:

- VS: Visibility
- FP: Customer Focus
- KP: Penta-helix Collaboration
- SC: Supply Chain Agility

ST: Sustainability

KI: Medical Device Industry Self-Sufficiency

Based on the structural model presented above, the following structural equations were established:

$$Y_1 = a + 0.394VS + \epsilon \quad R^2 = 0.647$$

$$Y_2 = a - 0.138FP + \epsilon \quad R^2 = 0.647$$

$$Y_3 = a + 0.041KP + \epsilon \quad R^2 = 0.647$$

$$Y_4 = a + 0.240SC + \epsilon \quad R^2 = 0.647$$

$$Y_5 = a + 0.464ST + \epsilon \quad R^2 = 0.647$$

The model shows an  $R^2$  value of 0.647, indicating that 64.7% of the variance in the self-sufficiency of the national medical device industry is explained by the five key variables. The remaining 35.3% reflects external influences, highlighting the sector's systemic and socio-political complexity. As per Cohen's (1988) criteria, this represents a large effect size, affirming the model's strong predictive power despite cross-sectoral variability.

The findings of this study contribute a novel, empirically validated strategic model for enhancing the self-sufficiency of Indonesia's medical device industry. Synthesizing structural equation modeling with qualitative data from policy-makers, academics, and industry leaders, the study reveals six interdependent dimensions—Regulation & Policy, Visibility, Customer Focus, Pentahelix Collaboration, Supply Chain Agility, and Sustainability—as the foundation for industrial resilience and competitiveness. The model is anchored in the Pharmaceutical Resilience Theory, the Malcolm Baldrige Performance Excellence Framework, and the Penta-helix Collaboration Model, offering a comprehensive lens for understanding systemic transformation in the medical device sector.

Notably, Sustainability emerged as the most statistically influential variable ( $\beta = 0.464$ ;  $p = 0.010$ ), emphasizing the criticality of long-term viability in national industrial planning. This supports earlier works (Karmaker et al., 2022; OECD, 2021) asserting that sustainable industrial ecosystems are essential to national health security. Policy recommendations underscore the need for regulatory reforms that embed affirmative procurement, fiscal incentives for green technology adoption, and end-to-end innovation funding. Additionally, workforce development through vocational health-tech education and investment in circular economy practices—including waste management, product lifecycle tracking, and eco-design—are imperative for sustainable competitiveness.

In contrast, Customer Focus, while conceptually important, did not show a statistically significant effect in the structural model. This suggests a misalignment between industry output and user expectations—a gap mirrored in global literature on health innovation (Yang & Yin, 2023). To resolve this, the study advocates a paradigm shift toward user-driven innovation (UDI), emphasizing participatory product design involving medical professionals and patients, digitalized feedback systems, after-sales service, and demonstrative public communication. Such measures are expected to strengthen user trust, drive adoption of local products, and enhance product-market fit.

The strategic dimension of Visibility reinforces the role of digital transformation in promoting domestic products. Integrated dashboards, AR/VR-enhanced catalogs, blockchain-based traceability, and national branding strategies are identified as levers to increase stakeholder awareness and public trust. The formation of a national penta-helix coordination body is proposed to institutionalize the visibility agenda and prevent fragmentation of initiatives.

Penta-helix Collaboration, particularly when aligned with adaptive regulation, emerges as a catalytic enabler for industrial growth. The model promotes the government as a systemic orchestrator—facilitating innovation consortia, harmonizing cross-ministerial policies, and embedding Regulatory Impact Assessment (RIA) as a design principle for responsive regulation. This is in line with global best practices in innovation governance (Maci, 2022). Open innovation ecosystems, built on risk-sharing mechanisms and regulatory sandboxes, are further recommended to accelerate the domestic commercialization of health technologies.

Despite its limited statistical weight, Supply Chain Agility was highlighted qualitatively as a critical enabler in times of public health emergencies. The COVID-19 pandemic and subsequent global disruptions underscore the need for real-time digital logistics systems, diversified and localized raw material sourcing, and collaborative networks for adaptive manufacturing. Strategic actions include the establishment of a national medical logistics unit,

implementation of predictive technologies (e.g., digital twin, IoT), and capacity-building in technopreneurship and adaptive logistics management. These interventions are expected to strengthen the sector's responsiveness to future systemic shocks.

Collectively, the model encourages a shift from fragmented, supply-side industrial strategies toward a coherent, demand-driven, and resilience-oriented framework. By aligning innovation with national health priorities, promoting digital and regulatory modernization, and embedding inclusive, sustainable practices, the model holds practical relevance not only for Indonesia but also for other emerging economies. It offers a transferable framework for countries seeking to balance industrial growth with health system resilience in a post-pandemic global landscape.

## 4. Discussion

This model articulates a multidimensional roadmap for industrial self-sufficiency. The dominant role of sustainability reflects global shifts toward ESG compliance and long-term investment strategies in industrial transformation. Penta-helix Collaboration, redefined here as a catalytic rather than supportive force, highlights the importance of governance platforms that go beyond symbolic inclusion. Customer focus and visibility indicate that trust and user engagement are essential in shifting procurement behavior toward local innovation. Furthermore, supply chain agility remains foundational in enabling import substitution and manufacturing resilience.

The study's novelty lies in empirically integrating theoretical constructs with stakeholder-derived indicators—bridging policy, governance, and operational spheres in a unified strategic model.

## 5. Conclusion, Implications, and Limitations

### 5.1 Conclusion

This research confirms that achieving national medical device industry self-sufficiency in Indonesia requires a transformation spanning regulatory reform, innovation visibility, agile logistics, user-centered design, and sustainability frameworks. The validated strategic model presents a comprehensive guide for policymakers and ecosystem actors to drive industrial independence and public health resilience.

### 5.2 Theoretical Implications

- Operationalizes abstract resilience frameworks into actionable constructs
- Extends Malcolm Baldrige and pharmaceutical resilience models to emerging-market industrial policy
- Demonstrates the strategic role of Pentahelix governance beyond collaboration rhetoric

### 5.3 Managerial Implications

- Encourage co-creation with clinicians and end-users
- Build smart supply chains with domestic sourcing and AI-based logistics
- Adopt strategic tools (e.g., Balanced Scorecards) to measure and manage performance
- Promote innovation hubs and open platforms for SME and academic partnerships

### 5.4 Regulatory and Policy Implications

- Establish a 2025–2045 National Roadmap for Medical Device Independence
- Create digital regulatory ecosystems interoperable across MoH, MoI, BPJS
- Incentivize local innovation through green finance and fast-track licensing
- Build transparency via national platforms such as SIINAs and OSS-RBA

### 5.5 Limitations

- Limited representation from peripheral regulators and financial sectors
- Cross-sectional design limits temporal insights
- Social desirability bias from institutional respondents
- Restricted access to internal regulatory documents
- Excludes external shocks (e.g., geopolitical, pricing) in modeling resilience

## 5.6 Future Research Directions

- Develop dynamic circular economy models for health technology
- Evaluate the impact of national visibility campaigns on domestic adoption
- Simulate adaptive supply chains under external volatility
- Explore clinician-led device co-design models
- Analyze governance architecture for collaborative innovation platforms

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