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Integrating toyota production system for sustainability and competitive advantage in medical device software design

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Abstract

This research explores the integration of the Toyota Production System (TPS) and sustainability into the software design and development processes of a medium-sized medical device company dealing with resource constraints and evolving customer requirements. Through an analysis of TPS principles and how they relate to manufacturing and software development challenges, the research seeks to strengthen efficiency and competitiveness. It provides an adaptable implementation plan that fosters a competitive strategy and promotes sustainability through efficient software practices. The paper presents a roadmap for systematically integrating TPS and sustainability in alignment with international best practices, positioning the company to thrive in the expanding medical software market. This framework addresses immediate operational issues while laying the groundwork for long-term success and compliance with industry standards.

Keywords: Business competitive strategy, Toyota Production System (TPS), lean production, sustainability, software design, manufacturing

INTRODUCTION

Numerous companies have focused on improving operations through efficient approaches and sustainable practices in the present competitive business landscape. The Toyota Production System (TPS), which



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employs lean concepts and continuous improvement programs to boost productivity across areas, is widely regarded as a transformative approach. Originally developed for manufacturing, it is known that TPS has transcended its automotive roots to find applications in sectors such as software, healthcare and construction. In software design and development in the medical device industry, challenges such as prolonged lead times and suboptimal resource utilization are prevalent. By applying lean manufacturing methods, organizations can align their management activities with TPS principles, streamline processes, and achieve greater overall efficiency. TPS emphasizes a process-based approach and waste reduction, significantly enhancing operational effectiveness and paving the way for lean software development techniques. This approach aims to reduce lead times and improve product quality while addressing the complexities of software development, including material modeling, code development, and parameter modifications. In medical device manufacturing, where efficiency and sustainability are paramount, incorporating TPS principles into software design and development processes can yield substantial benefits.

The significance of this research lies in its potential to streamline software design and development procedures within the medical device manufacturing process. By applying TPS concepts and lean software development, this study provides valuable insights for organizations seeking to enhance their software development processes. It explores how TPS methodologies contribute to waste reduction, increased efficiency, and the cultivation of sustainability as a competitive advantage. The study aims to identify practical benefits through qualitative examination, making it a valuable resource for researchers and industry practitioners alike.

The objectives of this research are to analyze manufacturing and software design processes, assess the application of TPS principles and sustainability strategies in software development, identify challenges and opportunities aligned with TPS benefits, and develop a systematic framework for achieving a competitive advantage. The study proposes an implementation strategy for a manufacturing medical device company, referred to as a medical device company, to maintain confidentiality. While the central hypotheses include that addressing software development challenges with TPS practices improves lead times and enhances development quality, the ongoing research stage of the software development process limits the feasibility of hypothesis testing. Instead, the study will provide insights by analyzing best practices and literature to guide software development improvements based on successful TPS and lean methodologies.

This research examines the theoretical feasibility of using TPS principles in the development of medical device software. Specifically, it attempts to provide a conceptual framework for better efficiency, quality, and compliance in medical device software development by examining how the concepts of TPS map into the unique requirements of this industry. While this study presents a theoretical framework for applying TPS principles to medical device software development, it is important to acknowledge its limitations. First, the research references relevant case studies from existing literature, as a full-scale implementation or case study was not feasible due to the company's early developmental stage, which requires additional time for data collection and compliance with strict medical device regulations. Additionally, the focus on the initial stages of product development may not fully capture the complexities that arise in later phases of the product lifecycle. Second, specific company data could not be included due to data confidentiality constraints. Third, the simulation tool analysis aimed to test the frameworks and TPS principles, providing valuable insights; however, it was limited by factors such as modeling expertise and data availability. Finally, the study does not delve into broader business considerations, including finance, sales, and marketing. Despite these limitations, this research serves as a valuable starting point for organizations seeking to optimize their medical device software development processes, offering a conceptual foundation for future empirical studies and more comprehensive investigations.

Literature review

Companies strive for long-term sustainability through advancements in operations, strategy and products. TPS principles emphasize continuous improvement and waste reduction, which have demonstrated effectiveness in manufacturing and show potential for software development. Sustainability is necessary for long-term success that combines social, environmental and economic factors. The study examines TPS and sustainability synergies in medical device manufacturing software design and development. It examines fundamental elements, advantages, challenges, and opportunities to ensure superior quality.

TPS and its foundation

The TPS traces its roots to the innovative work in automated looms of Sakichi Toyoda and Kiichiro Toyoda who perpetuate this legacy^[1]. TPS was developed under Kiichiro's leadership to solve economic issues and it embodies continuous improvement, waste reduction and respect for people, all of which are essential for organizational effectiveness^[2]. Originally developed for lean manufacturing, TPS greatly improves operational effectiveness, product quality and revenue generation^[3].

The Toyota Way 4P model, a pyramid-shaped framework, emphasizes philosophy, process, people, and partners. Its foundation is a mindset focused on providing value to society and consumers. It builds on lean principles to reduce waste and improve operational efficiency. The Toyota Way incorporates fourteen principles, including long-term decision-making, workflow optimization, and a "pull" system^[4,5]. Techniques such as visual control facilitate issue identification, while reliable technology supports target achievement; equitable task distribution, prompt issue resolution, and standardized procedures further promote efficiency. Developing informed leaders, building cohesive teams, establishing robust partnerships, and conducting continuous evaluations are essential to constructing a robust framework for organizational success and efficiency. This approach aligns with Toyota's fourteen management principles, which emphasize long-term perspectives, problem-solving and leadership^[6]. The TPS is a structured and organized methodology of production that maintains emphasis on efficiency and quality. Conceptually, it may be envisioned, for descriptive purposes, as a house with four key components: the first pillar is automation with human intelligence or Jidoka, the second pillar is eliminating waste or just-in-time, with the roof for customer focus, the foundation is standardization and operational stability and the center is the heart, its people. The guiding principles of the TPS are continuous improvement, customer satisfaction, high quality at lower cost, and in the shortest period. While similar to lean production, TPS focuses on the system as a whole rather than the various tools^[5].

Benefits of the TPS

Studies indicate that implementing TPS in practice leads to significant improvements. Lean manufacturing techniques, which are essential to TPS, help improve revenue, product quality and operational performance^[7,8]. Companies that use TPS see significant improvements in quality, lead time, cost, and employee engagement^[4]. TPS focuses on aspects such as continuous improvement, waste reduction, and adaptability^[3,5]. TPS can facilitate improved supply chain management, consumer satisfaction, and employee empowerment^[9-11]. Additionally, it can help with cost reduction, environmental sustainability, and overall organizational performance^[5,11,12]. TPS also guarantees a secure workplace and harmonizes company goals with customer demands^[11,13].

TPS in the software design and development

Applying the TPS to software design reveals similarities between customer-centric methods and waste elimination^[14] which recognize the challenges associated with software development. Through a just-in-time strategy, Kaizen for continuous improvement, and successful collaboration in cross-functional teams, TPS

concepts are highlighted to increase productivity and quality^[15]. Lean software development emphasizes minimum non-value-added processes, continuous testing and incremental delivery^[16]. Integrating TPS principles with lean approaches ensures that software solutions are of high quality, offer greater productivity, and are focused on their customers.

Sustainability in software development from the perspective of a medical device company

Numerous studies have explored the intersection of software development and sustainability. A particular study highlights the potential of integrating sustainability dimensions and waste management into software development processes^[17]. Another study emphasizes the crucial role of technology adoption in promoting sustainable development, and compares structured and agile software development methodologies in terms of their potential to contribute to sustainability goals^[18-20].

This is consistent with TPS principles as supported by research that demonstrates the positive relationship between lean processes and manufacturing sustainability^[21]. Applying TPS principles improves sustainability and organizational performance by increasing productivity and reducing waste. For instance, an organization that specializes in orthopedic and surgical instruments in the medical device business may gain an edge over its competitors by optimizing its software development, minimizing waste, and implementing TPS-based sustainable processes^[22].

Opportunities and challenges in integrating the TPS

TPS adoption brings a variety of possibilities and challenges. A study highlights the need for culture transformation and personnel training while addressing challenges with system integration and continuous improvement^[23]. The lack of competency among the workers on the shop floor was considered as the primary barrier^[24], indicating the importance of knowledge management and technical ability throughout implementation^[25,26].

TPS has its roots on the Toyota philosophy, which prioritizes waste reduction, optimized processes, and continuous improvement. It is a broader framework that offers the potential for wider process improvement^[5,27-29]. In contrast, Scrum is a subset of Agile with an emphasis on agility, flexibility, and collaboration. While Scrum is effective for software development^[30], it may have limited applicability in other industries. TPS and Scrum both recognize the importance of continuous improvement with a focus on efficiency, but they prioritize different aspects. Scrum emphasizes short-term planning, sprints for flexibility, iteration and collaboration, while TPS is centered on long-term planning, waste reduction, customer focus and standardized work. Understanding these differences can help organizations choose the best approach or a hybrid for their specific needs, especially in industries combining software development and manufacturing.

Additionally, potential benefits such as waste reduction and revenue growth have been highlighted for technological possibilities which include improved flow, enhanced cybersecurity, data analytics, and flexibility^[23]. However, challenges including data security and reluctance to change need to be addressed. Though strategy alignment and cost-benefit evaluations are essential, adopting technology such as cloud computing and 3D printing has advantages.

In summary, TPS presents advantages, but it still requires thorough planning for effective implementation^[23]. This study generally provides insights on TPS applications in a variety of areas, guiding future studies and practical initiatives.

METHODS

The method employed in order to achieve the objectives of the study focuses on evaluating the application of the TPS and sustainability in software design and development at a medical device manufacturing company. The methodology that has been selected includes analysis, research data and literature reviews to provide insight on the effectiveness and importance of TPS and sustainable practices. The methodology aims to examine the relationship between TPS principles and sustainability that guide the design and implementation.

The review of the literature focuses on important factors, particularly the TPS principles, sustainability in software design and the challenges faced by medical device manufacturing. Empirical research expands on this by providing practical insights into TPS implementation. The analysis phase entails reviewing quantitative data, such as performance metrics, to identify trends and potential for improvement.

The methodology proceeds with a structured approach including reviewing TPS and sustainability concepts, assessing current processes, benchmarking best practices and analyzing existing practices and success criteria. This approach involves the development of a strategy framework for operational excellence which incorporates TPS and sustainability principles.

Document analysis, manufacturing data reports, observation, research papers and industry data are some of the data-gathering methods employed. These methodologies offer an in-depth understanding of current practices and industry standards. The relevant insights are then determined utilizing qualitative and quantitative approaches such as statistical analysis and theme analysis.

In general, this method involves an in-depth review of software design and development processes in medical device company operations with the aim of improvement.

RESULTS AND DISCUSSION

The industry position of the medical device company was analyzed through the business frameworks of Porter's Five Forces, SWOT, VRIO, and PESTLE, which had certain insights on competitive dynamics, internal strengths and weaknesses, and external opportunities and threats. The research study also explored industry trends, studied the available literature on TPS practices, challenges, and sustainability, and checked compliance with international standards of the firm such as International Organization for Standardization (ISO) 13485 and the International Electrotechnical Commission (IEC) standards. These findings will provide a clear understanding of the business competitive situation, future areas of improvement, and opportunities for sustainable growth. In relation, internal analyses from the study on regulatory compliance and ISO will try to identify TPS alignment and sustainability challenges and opportunities using quality management system (QMS) information, production reports, and simulations. This thorough study consequently provides a basis for recommendations for future development and improvement.

Strategic analysis and market outlook

In a medical device company, a strategic analysis examines market dynamics using frameworks such as Porter's Five Forces, PESTLE, VRIO and SWOT. Research studies provide valuable insights that guide improvements, emphasizing software development, agile practices, and industry feedback. The strategy has to be aligned with the industry benchmarks and also capitalize on new opportunities. The main firms that constitute the market shares in the global orthopedic device market are Johnson & Johnson with 20%, Medtronic with 10%, Smith & Nephew with 5%, Stryker with 18%, and Zimmer Biomet with 15% share. Additionally, 32% of their shares are spread across various businesses that are growing steadily as a result of

technology improvements which demonstrate a high degree of concentration. High cost of implants is one of the ongoing challenges. The orthopedic device market in Southeast Asia was projected to grow by 6.43% yearly and reach US\$0.97 billion in 2023^[31-33].

Examining competition and strategic landscapes

The analysis of the competitive landscape of a medical device company, employing Porter's Five Forces framework, reveals high entry barriers due to substantial research and development (R&D) costs and stringent regulations. Supplier bargaining power is moderate, influenced by alternative suppliers and resource uniqueness. Buyers have great influence because of alternative substitutes and collective bargaining. There is some risk of substitutes balanced by the demand for orthopedic devices in critical cases. Intense competitive competition requires innovation, effective pricing, and understanding of the market.

Externally, political factors impact operations through government regulations, necessitating compliance and adaptability. Demand is driven by social factors such as aging populations and health awareness, while costs and viability from a financial perspective are influenced by economic stability. Rapid advancements in technology offer opportunities that also require a focus on data security. Legal considerations focus on adherence to regulations and maintaining intellectual property, whereas environmental considerations influence consumer perceptions and new product development, which results in a greater focus on sustainability.

Internally, the medical device company, using the VRIO evaluation, identifies valuable but common resources such as skilled teams and established relationships. Intellectual property offers a temporary advantage, while regulatory compliance, organizational structure, and project management practices are valuable yet common. SWOT analysis highlights strengths, which are quality products, innovation, distribution network, R&D, brand reputation, and ISO 13485 certification. Weaknesses can include an inadequate level of sustainability focus with a small market share, dependence on suppliers and the concentration on the local market. The growth in demand, international markets, innovations in technology, partnerships and assistance from governments offer numerous opportunities. The competition, price sensitivity, regulations, technical obsolescence, changes in the economy, and limited international exposure are all presenting potential threats.

This study utilizes Porter's Five Forces, SWOT, PESTLE, and VRIO frameworks to evaluate the integration of the TPS with sustainability in a medical device company software design. Porter's analysis highlights high entry barriers due to R&D costs and regulations, limiting TPS adoption. The SWOT analysis reveals strengths in product quality but identifies weaknesses in sustainability focus and market share. PESTLE indicates that regulatory compliance and technology drive TPS implementation, while training gaps hinder progress. The VRIO framework suggests that while resources are valuable, there is a certain commonality that restricts the competitive advantage. Comparative analysis reveals inefficiencies and misalignments with lean practices. Overall, while studies on TPS and sustainability are growing, a gap remains in their effective integration into software design processes, emphasizing the need for a structured approach.

These challenges are further underscored by strategic insights from a 2020 global survey of 355 medical device industry senior managers reveal challenges with shifting regulations (74%), product development complexity (47%), pricing (37%), funding (29%), talent retention (29%), competition (24%), tech adaptation (17%), and reimbursement changes (14%)^[34]. These insights primarily provide a robust understanding of challenges in the competitive medical device landscape.

In summary, integrating TPS principles with sustainability is vital for a medical device company to navigate regulatory complexities and enhance competitiveness. By adopting a structured approach to TPS, organizations can improve operational efficiency and product quality, positioning themselves for success in a rapidly evolving market.

Analysis of the current practices of a sample medical device company

The medical device company under consideration conforms with international standards, including ISO 14971 for risk management and ISO 13485 for QMS. Additionally, it complies with FDA 21 CFR Part 820, which guarantees quality and regulatory adherence for both local and U.S. markets. Its software design plans must adhere to IEC 62304, and electrical safety has to comply with IEC 60601-1, while ASTM International standards ensure material safety and approval.

Significant percentages of nonconforming products are used as is (7.96%), scrapped (8.22%), and require rework (9.61%); nonetheless, the production analysis identifies opportunities for improvement. Main root causes involve human error, setup/trial piece issues, and process challenges. Corrective and Preventive Action (CAPA) reports highlight human factors (80%) that impact quality systems, recalls, and standards, with corrective action taken.

Resolving human errors, improving product quality, and optimizing operational efficiency may be accomplished simultaneously by adhering to continuous improvement objectives and implementing TPS principles which include error-proofing and standard work. Adhering to best practices and gradually implementing TPS integration can assist a company in demonstrating its commitment to regulatory compliance, continuous improvement and efficient medical device manufacturing.

The recent advancement in the development of software for medical device companies underlines an urgent need to integrate QMS and lean methodology synergistically. New approaches have been developed that merge principles from the TPS in combination with ISO standards, such as ISO 13485 and ISO 14971, in an effort to promote better operational efficiencies, regulatory compliance, and risk management. They maximize the product life cycle from design through development and building onto distribution by using value stream mapping, just-in-time practice, and continuous improvement. Additionally, they introduce a comprehensive set of metrics to monitor performance at each stage, fostering a data-driven approach to quality and risk management. Such innovations address the specific challenges faced by medical device manufacturers and contribute to the advancement of best practices in quality engineering and risk management within complex industries.

Comparative analysis and strategic alignment

In this section, a comprehensive analysis comparing best practices in the medical device industry with TPS principles is evaluated to highlight the possible advantages of methods based on lean manufacturing where the alignment of risk management, quality management, regulatory compliance and customer-centric approaches was studied.

Comparison with TPS principles and medical device industry best practices

Industry best practices and TPS principles comparison: commonalities exist between medical device industry practices and TPS principles emphasizing waste reduction and standardized work processes for improved efficiency.

Survey on effectiveness of FDA regulations: of the 107 healthcare executives interviewed, 41% reported being neutral, 18% considered the regulations ineffective, and 7% found them very ineffective, indicating a range of viewpoints on FDA regulations^[35]. Addressing possible regulatory loopholes might improve flexibility and competitiveness in medical device company operations.

TPS integration compatibility with international standards: [Table 1](#) compares how the TPS aligns with ISO 13485, IEC 62304, and IEC 60601-1 standards. The table highlights key areas where TPS practices can be integrated to ensure compliance, enhance quality management, improve processes, manage risks, maintain documentation and traceability, meet regulatory requirements, and develop personnel competence. It offers insights into the compatibility and potential benefits of adopting TPS principles within the medical device industry.

Comparative analysis of best practices and TPS principles: a thorough comparison explores regulatory compliance, quality management, risk mitigation, documentation, and customer-centric approaches; also, as shown in [Table 2](#), it demonstrates how TPS can promote operational excellence and continuous improvement within a medical device company.

TPS principles alignment with sustainability: [Table 3](#) identifies the link between TPS principles and sustainability goals such as minimizing environmental impact, energy efficiency improvement, and stakeholder engagement. International standards guiding the current practices of the medical device company are based on quality management, risk management, and safety requirements. However, such standards are not focused explicitly on addressing sustainability. By integrating TPS philosophies, the company can enhance its operational competitiveness and market positioning while adhering to local regulatory laws. This approach not only mitigates environmental impacts but also fosters long-term sustainability within the business and the industry, ultimately ensuring the delivery of quality and safe products. [Table 3](#) emphasizes that it is not a matter of choosing between TPS principles and sustainability goals; rather, it highlights their interconnection, demonstrating how TPS implementation can facilitate sustainable practices that address environmental, social, and economic challenges.

Correlation study between TPS and sustainability: a study revealed a good link between strategic quality management and lean procedures, leading to sustainable and adaptable company operations^[36].

Business model archetypes for sustainability: the diverse archetypes of sustainable business models fall into three categories: technological, social, and organizational. Each category represents a different strategy in value creation with decreased environmental impact. Technological archetypes focus on innovation in the processes of production, efficiency in the use of materials, and energy conversion. Social archetypes focus on stakeholder welfare and community development. Organizational archetypes emphasize the structure and operation of businesses. If adopted, these archetypes can enable the possibility of a better future and enhancement of economic performance for businesses. The eight sustainable archetypes provide a guide for organizations to establish business models aligned with sustainability principles^[37].

Industry case studies and lean implementation examples

A study reveals that lean principles significantly benefit the medical device industry, resulting in a 50%-55% reduction in defects, a 48% decrease in cycle time and a 20% reduction in compliance audit efforts^[23]. Medtronic Xomed reported a 97% reduction in production lead time, a 54% decrease in order-to-shipment lead time, and a 38% reduction in the cost of shipped products, with additional achievements including a 40% increase in productivity, an 85% reduction in scrap, and a 57% reduction in rework. Baxter Healthcare

Table 1. TPS compatibility factors with the international standards analysis

	ISO 13485	ISO 14971	IEC 62304	IEC 60601-1
Quality management	The quality management principles and techniques outlined in ISO 13485 can be complemented by TPS. It can enable Orthopaedic International to continuously improve process effectiveness and enhance product quality	To ensure that effective risk management procedures are included into the quality management system, TPS can supplement ISO 14971. However, it is important to consider the guidelines outlined in ISO 14971	TPS can enhance the development of robust software life cycle processes outlined in IEC 62304	TPS can support the fundamental requirements for basic safety and performance as stated in IEC 60601-1 for medical equipment
Process improvement	TPS focuses on continuous improvement, waste reduction, and operational efficiency, which align with ISO 13485's goal of enhancing process effectiveness	TPS can support the identification, assessment, and control of risks in the entire product lifecycle as specified in ISO 14971	To increase quality and efficiency, TPS principles may be included into software development processes	To optimize operational efficiency and improve processes related to electrical medical equipment, TPS can be useful when aligned with IEC 60601-1
Risk management	To ensure the identification, assessment, and mitigation of hazards related to medical devices, TPS can be aligned with risk management procedures outlined in ISO 13485	TPS aligns with the principles and process framework specified in ISO 14971 for effective risk management of medical devices	TPS implementation should consider risk management requirements outlined in IEC 62304 for software-related risks	TPS to support the risk management processes specified in IEC 60601-1 to ensure electrical safety and essential performance of medical electrical equipment
Documentation and traceability	TPS practices are aligned with ISO 13485's documentation and traceability requirements for quality management processes	TPS considers the documentation and traceability requirements outlined in ISO 14971 for the management of risk information and decision-making	TPS implementation supports the documentation and traceability needs specified in IEC 62304 for software development activities	TPS practices ensure that documentation and traceability requirements specified in IEC 60601-1 are met for medical electrical equipment
Regulatory compliance	TPS can be implemented in a manner that does not compromise the organization's ability to meet regulatory requirements set forth by ISO 13485	TPS can help ensure compliance with regulatory requirements specified in ISO 14971 for risk management of medical devices	TPS implementation supports compliance with regulatory requirements outlined in IEC 62304 for software used in medical devices	TPS practices can align with regulatory requirements stated in IEC 60601-1 for medical electrical equipment
Training and competence	TPS implementation can consider training needs to ensure employees are competent in meeting ISO 13485 requirements	TPS will consider the training needs outlined in ISO 14971 to ensure personnel are adequately trained in risk management principles and practices	TPS principles can be incorporated into training programs to enhance the competence of personnel involved in software development processes compliant with IEC 62304	TPS can support the training and competence requirements specified in IEC 60601-1 for personnel involved in medical electrical equipment activities
Compatibility with standards	Alignment of TPS practices to the standard requirements to ensure no compromise in meeting regulatory and safety requirements	Ensure the identification, assessment, and mitigation of risks associated with medical devices in a way that TPS is aligned with risk management practices specified in ISO 13485 to minimize potential harm to patients and enhance product safety	Ensure no conflict with or compromise the organization's ability to meet the regulatory and safety requirements mandated by IEC 62304 in TPS implementation	While maintaining safety and regulatory compliance requirements, TPS practices should be in line with those outlined in IEC 60601-1

Source: the authors' work. TPS: Toyota Production System; ISO: International Organization for Standardization; IEC: International Electrotechnical Commission.

reduced costs by \$1 million with improved inventory turns from 25.5 to 41.9 and experienced a 74% improvement in the overall production lead time^[38]. With the use of lean practices and methodologies, the medical device manufacturer may use these cases as benchmarks to improve productivity and overall operational performance.

Alignment of TPS principles with software design and development

The analysis evaluates the implementation of TPS principles to several software design and development phases, including requirements analysis, design, coding, testing, maintenance and continuous improvement.

Table 2. Best practices compared to TPS principles analysis

Best practices	Company practices	TPS/Lean application	TPS practices
Regulatory compliance	Follow safety guidelines, implement quality management	Eliminate waste, ensure compliance, use visual management	Visual organization, error-proofing, waste reduction
Robust quality management	Implement a comprehensive quality system	Apply continuous improvement, conduct root cause analysis	Continuous improvement, root cause analysis
Risk management	Integrate risk mgmt. with TPS conduct assessments	Proactively identify risks, implement error-proofing	Proactive risk identification, error-proofing
Documentation and traceability	Maintain accurate documents, streamline processes	Implement electronic document management	Electronic document management, streamlined processes
Adherence to regulations	Observe statutory requirements, standardize work processes	Use standardized work instructions aligned with regulations	Standardized work processes, compliance
Customer-centric approach	Address customer needs, use value stream mapping	Reduce lead times, improve delivery schedules	Value stream mapping, timely delivery
Cross-functional collaboration	Encourage collaboration, teamwork, and empowerment	Bring representatives together for process improvements	Team empowerment, collaborative process improvements
Technological adaptation	Keep up with advancements, incorporate lean tools	Use automation and digital solutions for optimization	Automation, digital solutions for efficiency

Source: the authors' work. TPS: Toyota Production System.

Table 3. TPS and sustainability alignment analysis

TPS principles	Sustainability goals
Continuous improvement	Environmental impact reduction, energy efficiency, waste management, carbon footprint reduction, supply chain sustainability, social responsibility, stakeholder engagement, sustainable innovation, sustainable practices
Waste reduction	Environmental impact reduction, waste management
Standardized processes	Environmental impact reduction, waste management, supply chain sustainability, sustainable practices
Visual management	Stakeholder engagement
Pull systems	Supply chain sustainability
Value stream mapping	Environmental impact reduction, supply chain sustainability
Kaizen	Continuous improvement, sustainable innovation
Just-in-time production	Energy Efficiency, waste management, supply chain sustainability
Error proofing	Environmental impact reduction, sustainable practices
Cross-functional teams	Stakeholder engagement, sustainable practices
Empowered employees	Social responsibility, sustainable practices
Customer focus	Social responsibility, stakeholder engagement, sustainable practices

Source: the authors' work. TPS: Toyota Production System.

The goal of this integrated strategy [Table 4], is to achieve sustainable software development while maximizing efficiency and enhancing product quality. Table 4 also presents useful applications of TPS principles in the context of software development.

Software design and development process flowchart

The suggested software development process incorporates TPS principles throughout five phases where it seamlessly integrates with existing processes for continuous improvement in medical device manufacturing. TPS tools assist in the systematic requirement gathering process in Phase 1. Phase 2 concentrates on TPS for standardized work in software design. Phase 3 of the TPS methodology focuses on enhanced

Table 4. TPS principles and software design and development alignment analysis

TPS	Requirements analysis/spec	Design and architecture	Coding and implementation	Testing and validation	Maintenance and support
Continuous improvement	Solicit stakeholder feedback	Review and enhance design	Use flexible coding methods	Refine and expand test cases	Identify areas for improvement, apply upgrades
Waste reduction	Eliminate unnecessary requirements	Minimize design complexities	Eliminate unnecessary code	Implement efficient testing	Optimize maintenance by prioritizing issues
Standardized processes	Follow standardized approaches	Adhere to design principles	Implement coding standards	Follow standardized testing procedures	Establish maintenance procedures
Visual management	Use visual techniques for communication	Create visual representations	Utilize visual aids for code understanding	Use visual representations for tracking	Track system performance visually
Pull systems	Adopt pull-based approach	Implement pull system for design	Apply pull-based development	Implement pull system for testing	Utilize pull-based approach for maintenance
Value stream mapping	Map value stream to identify waste	Perform VSM for optimization	Apply VSM for coding	Utilize VSM for testing	Apply VSM for maintenance
Kaizen	Encourage continuous improvement	Apply Kaizen principles	Encourage developers to practice Kaizen	Implement Kaizen principles in testing	Embrace Kaizen for ongoing improvement
Just-in-time production	Apply JIT principles for delivery	Ensure timely design work	Minimize upfront coding, focus on functionality	Perform testing as needed	Address issues promptly for JIT support
Error proofing	Apply error-proofing techniques	Incorporate measures in design	Implement techniques in coding	Utilize measures during testing	Implement techniques in maintenance
Cross-functional teams	Foster collaboration for effective communication	Encourage collaboration between teams	Promote collaboration with developers and testers	Foster collaboration between testers and support teams	Promote collaboration with support teams and customers
Empowered employees	Encourage ownership and insights	Empower employees in decision-making	Allow autonomy in coding processes	Empower testers for high-quality software	Empower support teams for effective solutions
Customer focus	Gather and include customer requirements	Align architecture with customer needs	Prioritize customer requirements in coding	Test to meet customer expectations	Provide ongoing support for customer needs

Source: the authors' work. TPS: Toyota Production System; VSM: Value Stream Mapping; JIT: just-in-time.

implementation and testing to ensure continuous improvement. Phase 4 integrates TPS into verification, validation, and regulatory compliance, and Phase 5 involves external audits and compliance monitoring to ensure long-term improvement [Figure 1].

This strategy guarantees an organized software development process following industry standards. Utilizing TPS tools such as value stream mapping and Kanban reduces lead times and eliminates non-value-added processes. Emphasizing ISO 13485 compliance through the implementation of TPS-based risk analysis techniques such as hazard analysis and failure mode and effects analysis (FMEA) which facilitate problem-solving and productivity to improve customer satisfaction and competitiveness.

Phase 1 integrates TPS into software development, emphasizing the stakeholder engagement, waste elimination and risk analysis [Figure 2]. TPS tools such as value stream mapping, just-in-time, and Kanban enhance process efficiency. Risk management, utilizing TPS principles, focuses on preventive measures, employing tools such as SIPOC, VOC, QFD, FMEA, and hazard analysis. The strategy strives for an efficient software development process that is consistent with customer-focused and preventative philosophy of TPS^[39-44].

Phase 2 [Figure 3] standardizes software design architecture, modules, interfaces, and data models, aligning choices with TPS principles. Transparent documentation fosters collaborative understanding. The review process supports continuous improvement, with TPS integration presenting as a framework for clarity and effectiveness.

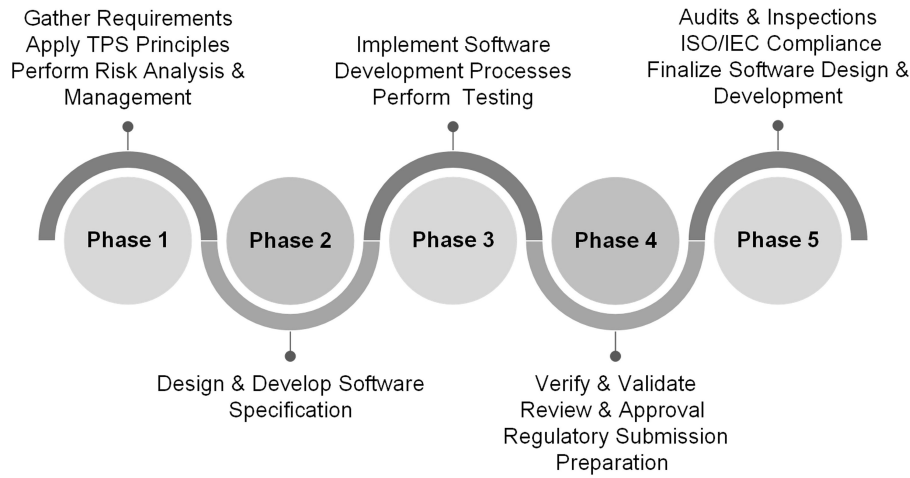


Figure 1. Proposed key phases of software development. Source: the authors' work.

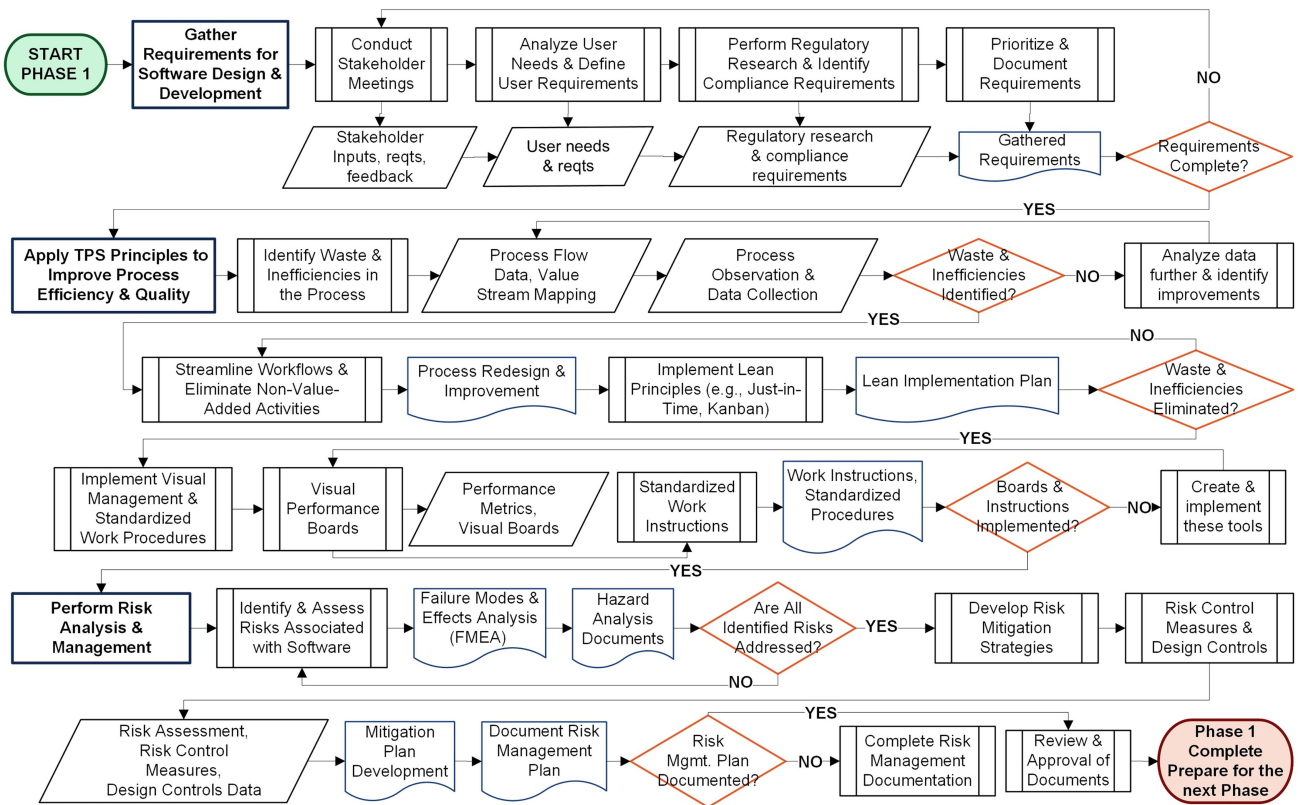


Figure 2. Phase 1 - process flowcharts of software design and development. Source: the authors' work.

Phase 3 [Figure 4] employs optimized environments and standardized coding processes to promote TPS in software development and testing. Testing emphasizes early defect detection and continuous improvement, which is in line with TPS's quality-centric approach.

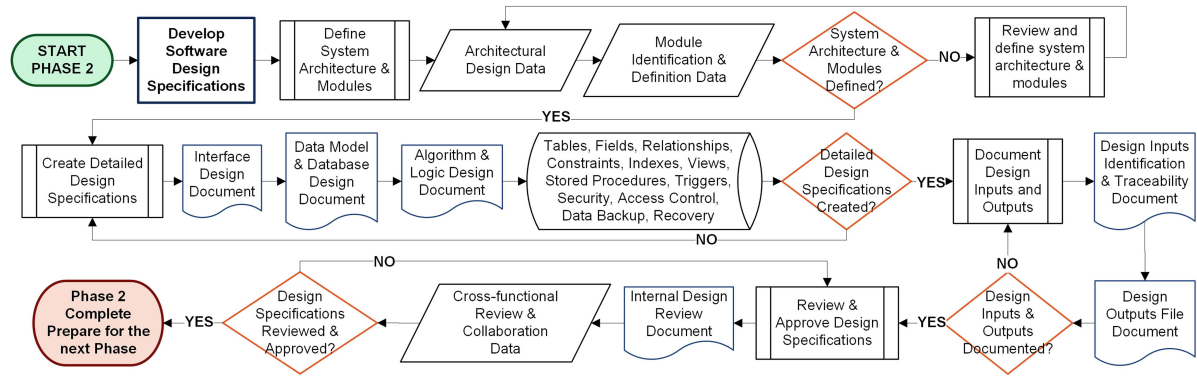


Figure 3. Phase 2 - process flowcharts of software design and development. Source: the authors' work.

Phase 4 [Figure 5] includes TPS in the verification and validation of software design, documentation and regulatory submissions. A customer-centric approach assures user acceptability testing, and documentation procedures encourage transparency and accuracy.

Phase 5 [Figure 6] includes external audits, compliance monitoring, and finalization. TPS principles drive systematic compliance, foster continuous improvement, and embed that in the organizational culture. The finalization process reflects TPS principles, ensuring operational excellence and quality assurance in software design and development.

The TPS principles are integrated into the proposed software design and development process flowchart of the medical device company to enhance its efficiency, quality, and compliance. A five-phase structured approach has been outlined, starting from requirement gathering and going up to regulatory submission, incorporating TPS tools such as value stream mapping, risk assessment, and continuous improvement. By aligning with TPS practices, the company will enhance workflows and reduce waste to ensure its overall process meets industry standards such as ISO 13485 and IEC 62304. The flowchart focuses on high-quality medical software devices by detailing the process in systematic and efficient ways that could help improve customer satisfaction and organizational competitiveness.

Measurement and metrics

Metrics are essential in software development for improving processes, planning projects, and measuring product quality^[45,46]. The medical device manufacturer may improve quality and efficiency by aligning TPS metrics with software metrics. The emphasis is on waste reduction, cycle time, and value stream analysis, which is integrated with software metrics for code quality, defect density, test coverage and productivity. Figure 7 illustrates how this connection increases customer happiness and streamlines procedures.

Proposed metrics

The proposed TPS-process metrics offer key performance indicators for evaluating the software development process, including cycle time, lead time, productivity, defect density, code churn, Work in Progress (WIP), throughput, takt time, Andon calls, changeover time, Jidoka, Kanban usage, poka-yoke, production flexibility and overall labor efficiency. These metrics assess speed, quality, resource utilization, workflow management, error prevention, continuous improvement, adaptability and overall resource effectiveness. The proposed TPS-Product Metrics provide indicators for assessing software product attributes and performance, including lines of code, function points, cyclomatic complexity, memory usage, response time, First-Time Yield (FTY), defect rate, scrap rate, productivity per labor hour, product

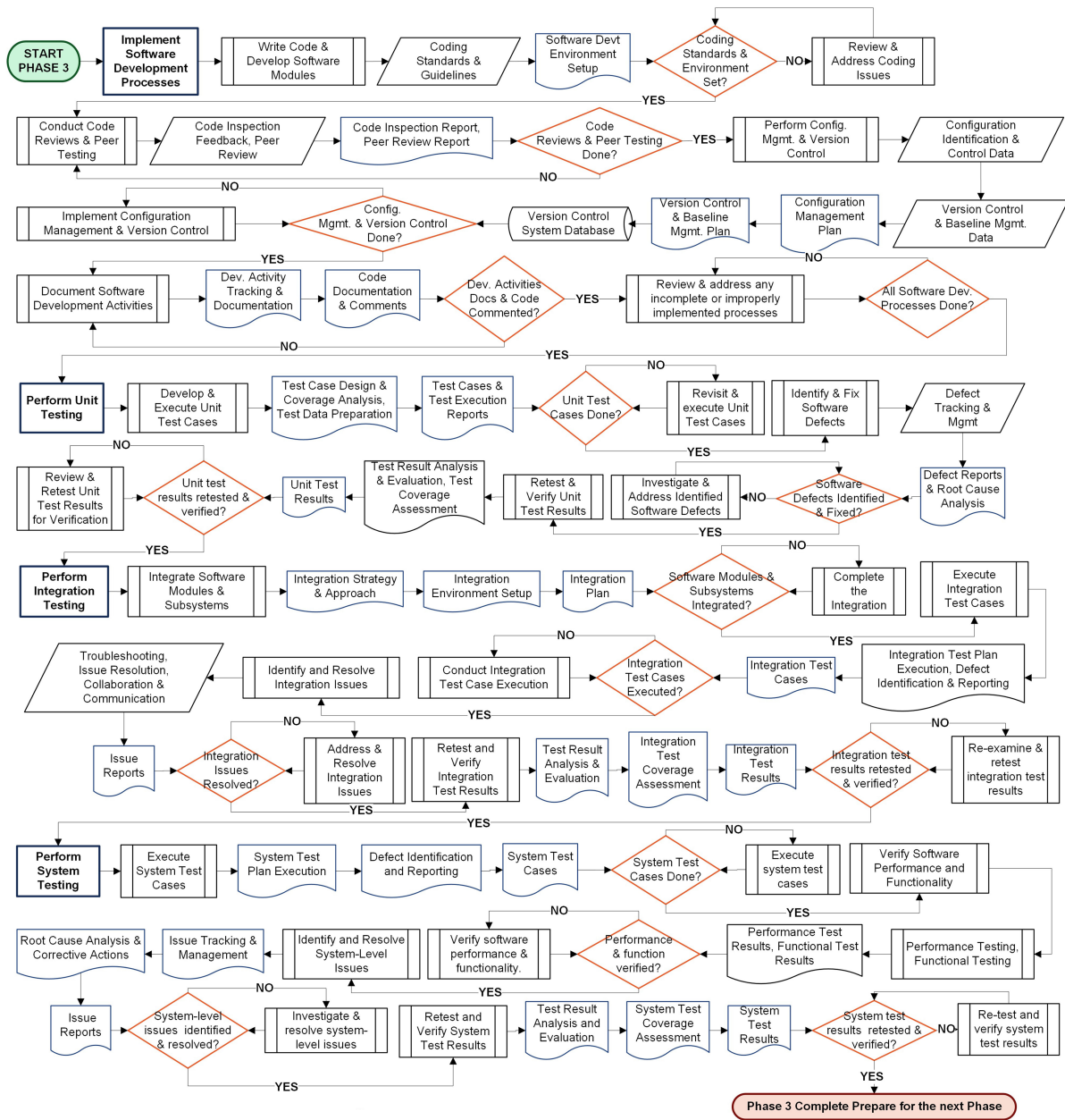


Figure 4. Phase 3 - process flowcharts of software design and development. Source: the authors' work.

development time and supplier lead time. These metrics offer insights into product complexity, functionality, codebase complexity, memory usage, user experience, quality, efficiency, time-to-market, and supply chain responsiveness.

The proposed TPS-project metrics use schedule variance, effort variance, resource utilization, Kaizen implementation rate, project lead time, and verify project cost variance. These metrics also provide information on project success, resource allocation, continuous improvement, project duration and budget compliance.

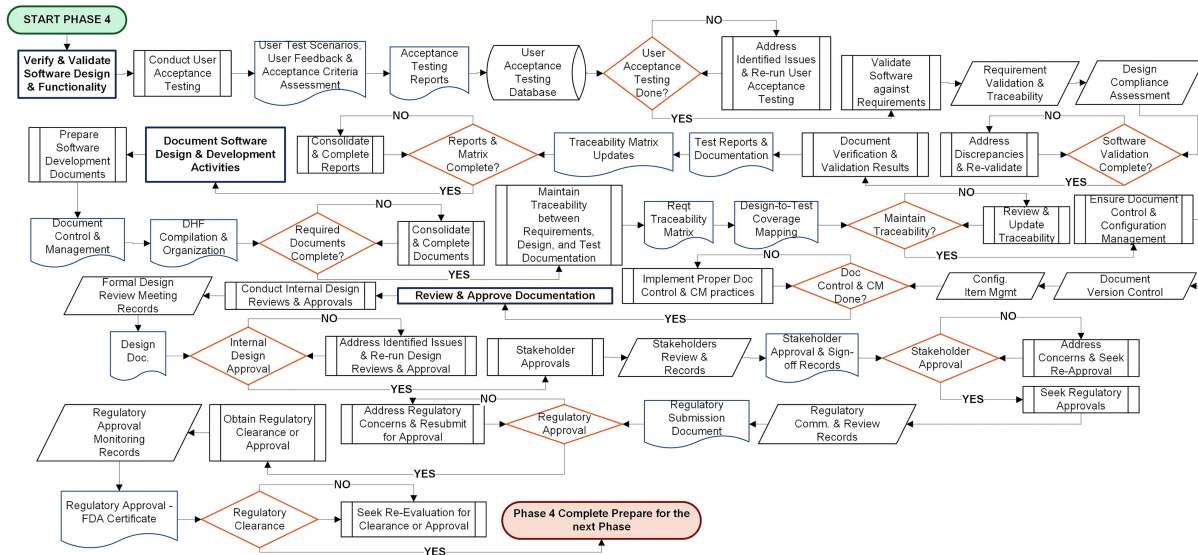


Figure 5. Phase 4 - process flowcharts of software design and development. Source: the authors' work.

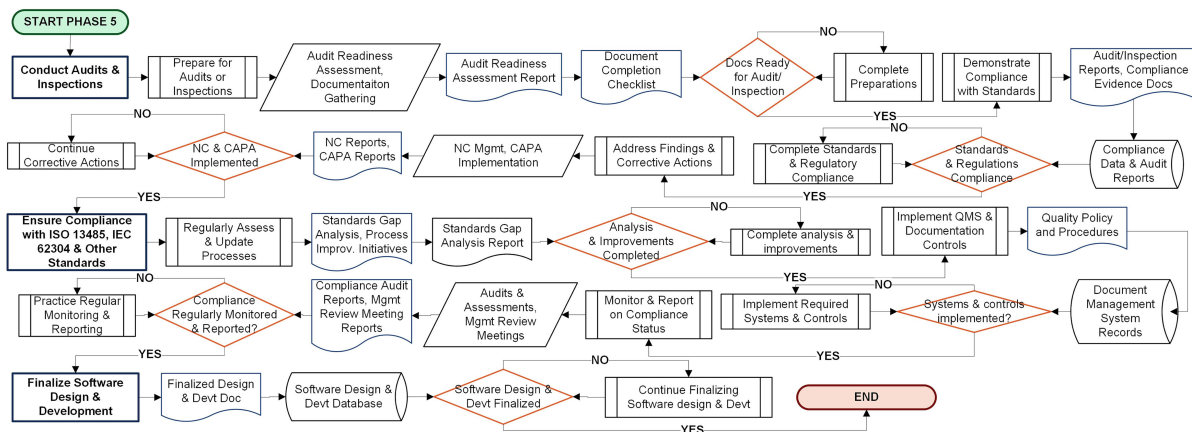


Figure 6. Phase 5 - process flowcharts of software design and development. Source: the authors' work.

The proposed TPS-Quality Metrics examine defect density, reliability, test coverage, maintainability, usability, bottleneck rate, Overall Equipment Effectiveness (OEE), and equipment downtime. These metrics measure software durability, accuracy of tests, reliability, maintainability, usability, overall efficiency, bottleneck identification and equipment downtime.

The proposed TPS-customer metrics provide measures such as net promoter score (NPS), customer feedback ratings, customer lead time, customer satisfaction, and customer returns. These metrics evaluate customer loyalty, sentiment, order fulfillment time, satisfaction levels, and return rates, promoting consumer relationships, loyalty and long-term success [Figure 7 and Table 5].

Proposed key phase metrics

The proposed metrics play a pivotal role in systematically evaluating and optimizing each phase of software design and development. To promote effective development, the metrics in Phase 1 placed a significant

Table 5. Proposed TPS metrics

		Details	Measurement
TPS process metrics	Cycle time	Time to complete a task	End time - start time
	Lead time	Time from task initiation to completion	End time - start time
	Productivity	Work completed per unit of time or effort	Work completed/Time or effort expended
	Defect density	Defects per unit of code size	Number of defects/Code size
	Code churn	Frequency of code changes	Number of code changes over time
	WIP	Tasks in progress	Count of tasks in progress
	Throughput	Rate of work completion	Units completed/Time taken
	Takt time	Time of production per required rate	Production time/Required rate
	Andon calls	Frequency of issue alerts	Count of Andon calls
	Changeover time	Time to switch production processes	End time - start time
	Jidoka usage	Adoption of automation	Measure utilization of Jidoka
	Kanban usage	Effectiveness of work-in-progress control	Adherence to Kanban principles
	Poka-yoke (Error-proofing)	Number of error-proofing mechanisms	Count of error-proofing mechanisms
	Production flexibility	Ability to adapt to changes	Measure adaptability and response time
	Overall labor efficiency	Overall labor efficiency	$(\text{Total actual labor hours})/(\text{total available labor hours}) \times 100$
	TPS product metrics	LOC	Total lines of code in the software
Function points		Measure of software functionality	Calculate based on user interactions, data inputs/outputs, and processing requirements
Cyclomatic complexity		Codebase complexity measure	Measure the number of independent paths
Memory usage		Memory consumed during execution	Measure memory utilization during execution
Response time		Software reaction speed	Measure the time from user action to software response
FTY		Percentage of defect-free products on the first attempt	$(\text{Defect-free products}/\text{Total products}) \times 100$
Defect rate		Number of defects in a time period	Number of defects/Total products
Scrap rate		Proportion of discarded products due to defects	$(\text{Defective products}/\text{Total produced Products}) \times 100$
Productivity per labor hour		Output per labor hour	Total output/Total labor hours
Product development time		Time from product conception to launch	Time of product launch - time of product conception
TPS project metrics	Supplier lead time	Time for suppliers to provide materials	End time - start time
	Schedule variance	Actual vs. planned schedule	Schedule variance = planned schedule - actual schedule
	Effort variance	Disparity between estimated and actual effort	Effort variance = estimated effort - actual effort
	Resource utilization	Efficiency of resource allocation	$(\text{Actual resource usage}/\text{Total available resources}) \times 100\%$
	Kaizen implementation Rate	Rate of implemented Kaizen initiatives	$(\text{Implemented Kaizen initiatives}/\text{Total Kaizen initiatives}) \times 100$
	Project lead time	Time to complete a project	Project completion date - project start date
TPS quality metrics	Project cost variance	Budgeted vs. actual project costs	Actual project cost - budgeted project cost
	Defect density	Defect rate per code size or functionality	$(\text{Number of defects})/(\text{size of code or functionality})$
	Test coverage	Proportion of code subjected to automated testing	$(\text{Lines of code covered by tests}/\text{Total lines of code}) \times 100\%$
	Reliability	Consistency of software performance	Measure the frequency of failures over a specified period
	Maintainability	Ease of modifying or extending software	Measure factors like code readability, complexity, and ease of change
	Usability	Ease of use and user satisfaction	Measure through user feedback surveys and usability testing
	OEE	Equipment efficiency gauge	$\text{OEE} = \text{availability} \times \text{performance} \times \text{quality}$
	Bottleneck rate	Rate of bottleneck limiting production output	$(\text{Output of bottleneck process}/\text{Total output}) \times 100$

	Equipment downtime	Non-operational time due to maintenance or breakdowns	End time - start time
TPS customer metrics	NPS	Customer loyalty and willingness to recommend	Calculate based on customer surveys
	Customer feedback ratings	Ratings and feedback about the product	Collect feedback through surveys or feedback mechanisms
	Customer lead time	Time to fulfill customer orders	End time - start time
	Customer satisfaction	Level of satisfaction expressed by customers	$(\text{Number of satisfied customers}) / (\text{Total number of customers}) \times 100$
	Customer returns	Rate of product returns due to defects	$(\text{Number of products returned by customers}) / (\text{Total number of products sold to customers})$

Source: the authors' work. TPS: Toyota Production System; WIP: work in progress; LOC: lines of code; FTY: First-Time Yield; OEE: Overall Equipment Effectiveness; NPS: net promoter score.

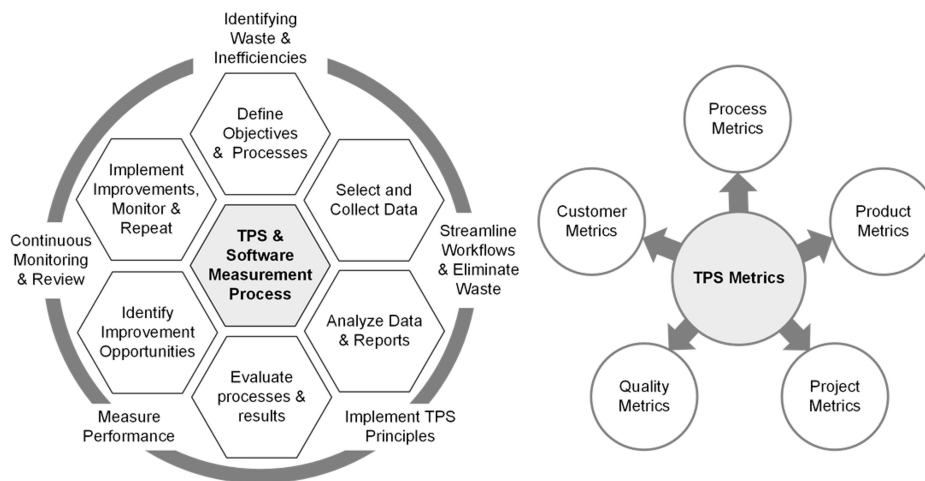


Figure 7. TPS and software measurement process and metrics. Source: the authors' work. TPS: Toyota Production System.

emphasis on effective requirement gathering with the implementation of TPS principles including comprehensive risk analysis.

Moving into Phase 2, the metrics shift their focus to the creation of precise and efficient software design specifications. Evaluating code quality, testing effectiveness, and compliance to configuration management requirements where Phase 3 and Phase 4 metrics adhere to software development processes, testing and verification/validation activities efficiently.

Advancing to Phase 5, the metrics extend their scope to cover external audits, ensuring compliance, and finalizing design and development aspects. Monitoring deployment success, audit readiness, compliance adherence, corrective actions and deployment success rates are all considered essential factors. At the same time, ensuring that all quality and regulatory requirements are satisfied is the primary objective.

In essence, these metrics collectively function as a comprehensive tool to optimize the entire software development process. The application guarantees compliance with standards and regulations while concurrently enhancing the quality and performance of the final software product; refer to [Table 6](#) for a detailed overview of the proposed metrics for each phase of software design and development.

Table 6. Proposed phases metrics for software design and development

	Details		Measurement and evaluation
Phase 1 metrics	Gather requirements for software design and development		
	Stakeholder Interviews	Comprehensive gathering of requirements	Count of conducted interviews
	Time to analyze user needs	Efficiency in defining requirements	Average time for analysis
	Compliance requirements	Alignment with regulations and standards	Count of identified requirements
	Prioritized requirements	Focus on critical development needs	Count of prioritized requirements
	Apply TPS principles to improve process efficiency and quality		
	Identified waste and inefficiencies	Quantify areas for improvement	Count of identified waste
	Non-value-added activities	Measure process streamlining	Percentage eliminated
	Time reduction in workflows	Impact of process redesign on efficiency	Average time reduction
	TPS implementation rate	Adoption of lean practices	Percentage implemented
	Visual mgmt. and standardized work	Adherence to standardized processes	Percentage implemented
	Perform risk analysis and management		
	Identified risks	Assessment of potential threats	Count of identified risks
	Time for risk assessment	Efficiency in risk management efforts	Average time for assessment
	Risk control measures	Actions to minimize identified risks	Count of implemented measures
Risk management plan completion	Comprehensive risk mitigation planning	Completion rate of the plan	
Phase 2 metrics	Develop software design specifications		
	Defined system architecture	Comprehensiveness of system definition	Count of defined architecture and modules
	Time for detailed design specifications	Efficiency in specification creation	Average time for detailed specifications
	Accuracy of design inputs	Precision and traceability	Percentage of accurate design inputs
	Proper documentation of design outputs	Completeness of design documentation	Percentage of properly documented outputs
	Design review cycle time	Efficiency of review and approval	Time for review and approval
	Design requirements traceability	Alignment of design outputs with req.	Percentage of traceability coverage
Phase 3 metrics	Identified and resolved design issues	Tracking and addressing challenges	Count of issues identified and resolved
	Percentage of design changes	Scope of modifications during development	Percentage of design changes
	Implement software development processes		
	Code quality metrics	Evaluate code quality (complexity, duplication)	Measurement of code complexity, duplication, etc.
	Code reviews conducted	Ensure code quality through peer review	Count of code reviews conducted
	Version control activity metrics	Track changes and maintain code integrity	Measurement of version control activity (e.g., commits, merges)
	Documentation completeness	Verify comprehensiveness of software documentation	Measurement of documentation completeness
	Percentage of code and modules developed	Track progress in code development	Percentage of code and modules developed
	Effectiveness of code reviews and peer testing	Assess impact on code quality	Measurement of defects identified and fixed during reviews and testing
	Compliance with configuration management	Ensure adherence to best practices	Compliance assessment with configuration management practices
Perform unit testing, integration testing, system testing/Verify and validate software design and functionality (Phase 4)			
Test coverage	Measure proportion of software covered by tests	Percentage of test coverage	
Defect density	Quantify defects per unit of software size	Number of defects per unit of software size	
Test pass rate	Track success rate of test cases	Percentage of test cases passed	
Test execution time	Evaluate efficiency of test execution	Measurement of test execution time	
Test coverage achieved	Assess comprehensiveness of testing	Measurement of code coverage, requirement coverage	
Integration tests and defects	Track progress and defects in integration testing	Count of integration tests executed and defects identified	

	Test result analysis metrics	Assess overall test results and defect leakage	Measurement of pass/fail rate, defect leakage rate
Phase 4	Review and approve documentation/Prepare regulatory submission		
Metrics	Document version control	Track document revisions and maintain version history	Monitoring of document revisions and version control activity
	Compliance audit findings closure time	Measure time to address and resolve audit findings	Evaluation of time taken to close compliance audit findings
	Regulatory submission approval time	Evaluate duration to obtain regulatory approvals	Assessment of duration to get regulatory submissions approved
	Stakeholder approval cycle time	Assess efficiency of obtaining approvals	Measurement of time taken to obtain approvals from stakeholders
Phase 5	Conduct external audits and inspections		
Metrics	Preparedness for external audits	Assess readiness for external audits or inspections	Evaluation of preparedness for audits or inspections
	Compliance with standards	Verify adherence to relevant standards and regulations	Assessment of compliance with standards and regulations
	Number of findings identified	Track and address issues or non-compliances	Count of findings identified and addressed during audits or inspections
	Effectiveness of corrective and preventive actions	Evaluate impact and efficiency of actions taken	Evaluation of effectiveness of corrective and preventive actions
	Ensure compliance with standards		
	Assessment and Improvement of Standard Compliance	Assess level of compliance and identify improvement areas	Measurement of standard compliance and improvement activities
	Implementation of quality management systems	Establish and maintain effective quality management systems	Evaluation of implementation and effectiveness of quality management systems
	Monitoring and reporting of compliance status	Track and report organization's compliance status	Regular monitoring and reporting of compliance status with relevant standards
	Finalize software design and development		
	Deployment success rate	Measure rate of successful software deployments	Evaluation of proportion of successful software deployments
	Production system uptime	Assess availability and reliability of production system	Measurement of time the production system remains operational
	Response time	Evaluate the time taken for software to respond to user actions	Monitoring of time taken for software to respond to user actions
	Number of incidents and problem resolution time	Track and address incidents and measure time to resolve problems	Count of incidents and evaluation of time taken to resolve problems
	Customer-reported issues and resolution time	Track customer-reported issues and assess the time to resolve	Monitoring of customer-reported issues and measurement of time to resolve

Source: the authors' work. TPS: Toyota Production System.

Framework and implementation strategies

The framework and implementation methodologies provided in this research seek to assist manufacturers of medical devices in adopting and implementing lean manufacturing strategies based on TPS principles. The framework considers specific challenges and peculiarities of the company alongside the software design and development area.

Existing frameworks for lean implementation

Lean frameworks highlight the need of adapting TPS strategies to specific company needs, which provides beneficial information for small and medium-sized organizations (SMEs).

Key findings from various studies on lean implementation frameworks for SMEs highlight the significance of change management in driving lean transformation^[47], integrating total productive maintenance (TPM), Six Sigma, and lean for holistic operational excellence^[48], and offering comprehensive frameworks guiding the structured adoption of lean practices^[49]. Detailed frameworks emphasize adaptation for SME challenges

in line with Plan-Do-Check-Act (PDCA) cycles^[50]; some focus on monitoring, regulating, and aligning with essential success factors for sustainable implementation^[51]. Theoretical frameworks can also strengthen SME commitment by offering practical lean manufacturing methods with defined performance metrics. The frameworks provide a structured approach for implementing lean principles, leading to improved efficiency, reduced waste, and enhanced overall performance.^[52,53,54] In another study, a Sustainable Lean Production Framework integrates lean Six Sigma concepts to satisfy sustainability goals^[55]. Additionally, a comprehensive framework was proposed to guide organizations, across industries, in overcoming lean implementation barriers and successfully integrating lean principles into their operations. This framework consolidates various lean perspectives, including barriers, principles, tools, and performance measures^[56].

Various TPS Frameworks, with the guiding principles and practices of TPS, emphasize competitiveness through productivity and waste elimination for cost reduction and growth^[57]. These frameworks focus on quality, efficiency and employee development beginning with small group activities and leadership support to meet organizational objectives. Flexible workforce and cost-saving strategies are critical factors.

A sample TPS roadmap for a medical device company

A specific TPS roadmap tailored to a medical device company is introduced, drawing inspiration from TPS principles. The roadmap in [Figure 8](#) depicts a strategy that will assist the organization in managing challenges, strengthening competitiveness and embracing sustainable practices. The primary goal is to apply TPS concepts to minimize waste, increase efficiency in software design and development, provide high-quality products, and achieve long-term success. The roadmap includes specific milestones that concentrate on unique elements of TPS.

The roadmap shown in [Figure 8](#) serves as a strategic guide for the company to adapt to TPS principles progressively, promoting a culture of continuous improvement and achieving improvements in productivity, quality, and customer satisfaction.

Exploring simulation tools for testing and constraints

Simulation tools have become indispensable for analyzing and optimizing complex processes across various domains, including software systems and project management. Notable studies have explored topics such as software development, resource allocation, and cost overruns, providing valuable insights into strategic project management, understanding project failures, and overseeing intricate initiatives.

The use of simulation tools has become essential in organizing and evaluating complex processes in a variety of fields such as software systems and project management. Relevant subject matter, including software development, resource allocation, and cost overruns, has been the focus of notable studies, which offer perceptions into strategic project management, comprehending project failures, and overseeing intricate initiatives^[58-68]. The integration of TPS principles in software development to improve business performance and sustainability is a special area of interest for simulation practitioners, who can use these findings to create efficient methods for implementation testing and experimentation. The simulation model aims to assess TPS impact, identify bottlenecks and evaluate efficiency while considering variables such as lines of code, staff expertise, productivity, project completion, and success. Among the constraints are the requirements for modeling expertise and the limitations of the AnyLogic software version that is currently used^[69,70]. The study focuses on simulation as an exploratory tool in the implementation approach of the company.

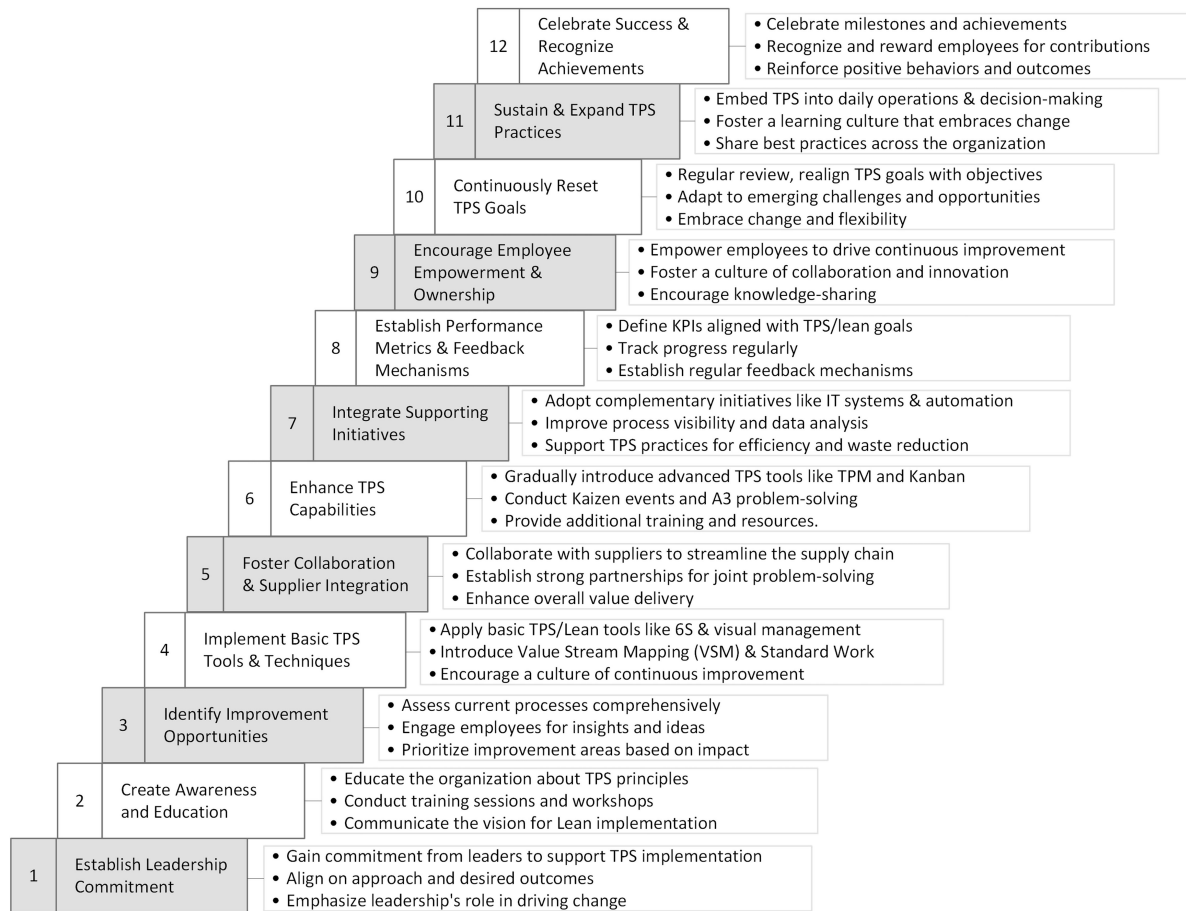


Figure 8. TPS roadmap strategy for a medical device company. Source: the authors' work. TPS: Toyota Production System.

RECOMMENDATION AND CONCLUSION

The recommendations and conclusions consider the objectives of the research, analysis, and findings. Exploring TPS integration for enhanced efficiency, quality, and sustainability in the software design, development, and manufacturing processes of a medical device company. Recommendations focus on TPS process improvement, integration, sustainability, and continuous improvement.

Recommendations

TPS process improvement and manufacturing streamlining

- Utilize TPS principles

- Use of visual management, just-in-time (JIT) manufacturing and task boards for transparency.
- Employ value stream mapping, Kanban and workshops for better understanding.
- Measure progress with metrics to identify bottlenecks, save time, and reduce waste.

- Process standardization

- Forming cross-functional teams that can define procedures and thoroughly document processes.
- Conduct regular reviews and metrics to ensure consistency in software testing.
- Track progress through TPS team meetings and monthly assessments for seamless integration and continuous improvement by seeking feedback and refining the plan.

- Streamlining manufacturing complexities
 - Utilize specialized teams for TPS tools, such as PDCA and value stream mapping, and task groups to handle production difficulties and ensure continuous improvement and compliance with regulations.
 - Regularly review and assess metrics for efficient team establishment and improved risk assessment rates.

Integration of sustainable practices

- Embrace sustainable practices
 - Integrate sustainable practices aligned with TPS principles into software development.
 - Focus on awareness, relevant practices, workflow integration, and continuous monitoring.
 - Monitor and assess learning session engagement for enhanced efficiency, waste reduction and continuous improvement.

Performance metrics and continuous improvement

- Establishing performance metrics
 - Define efficiency, quality, satisfaction, and sustainability metrics aligned with TPS tools.
 - Sustain departmental alignment, measure customer satisfaction with the NPS, analyze data using PDCA, and conduct regular reviews that can demonstrate performance by immediately adjusting to new requirements and completing audits.
- Promoting a culture of continuous improvement
 - Encourage cross-functional collaboration and track participation rates.
 - Establish open channels of communication and conduct frequent training sessions such as weekly "improvement huddles" to increase collaboration, reduce production cycle times and ensure continuous improvement through regular review and assessment.

Leadership and employee empowerment

- Leadership commitment
 - Initiate top-level communication emphasizing TPS principles and sustainable practices.
 - Enlist management as role models, integrate TPS into strategic planning, and ensure continuous improvement.
- Empowerment of employees
 - Launch a communication campaign to introduce TPS principles, establish idea-sharing platforms, develop training programs and implement a recognition system.
 - Conduct regular assessments to guarantee increasing engagement, improved competencies and sustained motivation.

Strategic partnerships

- Collaborate with industry experts
 - Identify experts with TPS implementation experience and develop a collaboration strategy.
 - Build partnerships, integrate expert opinions into the TPS strategy and maintain continuous engagement that encourages efficiency and continuous improvement.

Future studies and evaluation

- Improved experimentation studies
 - Apply TPS tools and principles to enhance software development studies to ensure accurate results through validation and statistical analysis.

- Demonstrate success through improved research, methodologies, clear TPS distinctions, continuous improvement and data analysis techniques.

Conclusion

This study significantly strengthens software design and development processes by effectively integrating TPS principles and sustainability measures into medical device manufacturing. It successfully uncovered various advantageous outcomes and benefits leading to an extensive and systematic framework and a robust implementation strategy. The harmonious integration of ISO standards and TPS not only ensures operational excellence and efficiency but also contributes to heightened customer satisfaction.

The strategic analysis conducted in this study delves into the challenges, opportunities and advantages associated with applying TPS principles in software design, aligning the strategy with the dynamic landscape of the industry. The proposed frameworks with the specifically developed metrics together with the adoption of TPS principles provide a well-defined roadmap. The strategy emphasizes leadership commitment, employee empowerment and continuous improvement. The inclusion of experimental testing adds invaluable insights, providing real-world validation that is indispensable for effective implementation. In summary, an essential driver for achieving software design excellence involves the implementation of TPS principles and sustainable practices. The study provides not only useful insights but also practical recommendations to foster growth, enhance operational efficiency, and sustain competitiveness in the ever-evolving landscape of software development.

Future research

Future study directions involve looking at the long-term impact, financial and economic implications, ethics, supplier collaboration, and potential challenges associated with TPS implementation. Longitudinal studies and economic evaluations are required to ensure long-term effectiveness and financial benefits. Comprehensive study alternatives include investigating ethical factors, collaborating with suppliers and developing simulation models.

Further research into TPS integration across the manufacturing process, as well as evaluations of flexibility and scalability, contributes to sustained growth. This thorough study establishes a framework to address the evolving challenges faced by the dynamic software design and development industry.

DECLARATIONS

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Authors' contributions

Conceived the study, conducted analysis, and interpreted the data: Lim LR

Contributed to the research design and provided mentorship and guidance: Tan AWK

Availability of data and materials

Data used for analysis, including information from Statista, are cited in the references. Access to the Statista repository requires a subscription.

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Both authors declared that there are no conflicts of interest.

Ethical approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

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