THE INFLUENCE OF TECHNOLOGICAL, ORGANIZATIONAL AND ENVIRONMENTAL FACTORS ON COMPANY PERFORMANCE IN SERIALIZATION SYSTEM IMPLEMENTATION IN PT BIOFARMA

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Abstract

A serialization system is a technological solution that enables product tracking and traceability by providing a unique identity for each product unit. This system can prevent the circulation of counterfeit products in the supply chain of pharmaceutical products. Companies must deploy this serialization system technology to comply with applicable requirements and maintain competitiveness. This study aims to determine the effect of TOE framework on the implementation of the serialization system on company performance using a survey/questionnaire method at PT Bio Farma (Persero). Statistical testing uses Structured Equation Modeling (SEM) to measure the relationship between variables. The test result identified that technological, organizational, and environmental contexts have a positive and significant impact on the serialization system's implementation at Bio Farma. The results also revealed that the implementation of the serialization system has had a positive and significant impact on company performance. This research can have good implications for companies and top management in providing appropriate and compatible technology support so that the adoption of implementation serialization technology can improve company performance.

Keywords: Traceability, Serialization, Technology Adoption, Organizational, Environment, TOE Framework

Introduction

Since 1980, the World Health Organization (WHO) has stated that the threat of circulating counterfeit or substandard products or products without a license has continued to increase and endanger patients (WHO, 2017). There have been several incidents that have caused side effects and even the death of the patient. The risk from the circulation of counterfeit drugs is a threat to patient safety, a threat to the industry (loss of profit, damage to reputation, loss of market position, etc.), and a threat to the health care system (Horalek & Sobeslav, 2017). The threat of the circulation of counterfeit products then becomes the basis for regulators to improve product supply chain processes (Pagonidis et al, 2020). Governments and regulators work together to develop regulations to protect legitimate pharmaceutical product channels by creating laws or regulations that encourage the industry to implement a global traceability system for products.

A serialization system is a technological solution that enables product tracking and tracing (traceability) by providing a unique identity to each product unit or units. Through the use of a unique code, such as a serial number or QR code, the system allows tracking of individual products, from the time of production to the process of distribution and consumption of the product. The main advantages of serialization systems are increased product safety, counterfeit product detection, increased supply chain efficiency, and compliance with regulatory requirements. In addition, serialization systems can also provide operational benefits such as improvements in inventory management and production monitoring (Thornton, 2018).

Implementation of new technology in business processes can boost productivity, drive company growth, and achieve competitive advantages. In addition, the implementation of new technology, besides requiring adjustments to business processes, may also have far-reaching implications for productivity, labor skills, income distribution, and well-being—even the environment. This can have a fundamental impact on the industry (Zong and Moon, 2023). Previous research has tested a lot regarding the implementation of new systems to see technology acceptance in the TOE framework, including mobile marketing applications, ERP, RFID, blockchain, and food traceability, as well as digital evolution and adoption of innovative technology (Maduku et al, 2016; Rafique et al , 2022; Raut et al, 2020; Anim-Yeboah et al, 2019; Angeles, 2012; Yavaprabhas et al, 2021; Duan et al, 2017; Brito da Silva et al, 2019; Pool et al, 2015; Wang et al , 2010; Wong et al, 2019; Yoon et al, 2020). In this study, the research model is based on the TOE framework originally designed by Tornatzky and Fleischer (1990).

In spite of this, previous studies have limited understanding of technology traceability adoption and implementation in pharmaceutical companies, especially in Indonesia. Thus, this study addresses these gaps through a case study of TOE framework on the implementation of a serialization system at a pharmaceutical company in Indonesia as intervening effect on company productivity.

Literature Review

TOE framework

This theoretical framework was introduced by Tornatzky and Fleisher in 1990. The focus of this theory is to look at the influence of intrinsic and extrinsic factors on the adoption of new technology and innovation processes by companies, which cover three aspects: technological, organizational, and environmental contexts. TOE has been applied to investigate the adoption of various types of high technology in many studies, such as RFID technology, information and communication technology, cloud computing, and so on. Adoption and commercialization of information technology can bring new opportunities and generate profits for businesses; thus, a large number of companies are constantly working to increase productivity and strengthen their competitive advantage through technological innovation (Baker, 2012).

The technological context includes all technological information both internally and externally available that can influence organizational technological innovation, whether the technology is currently used or is not yet available in the market (Baker, 2012). In this study, the technological context that can influence the serialization system implementation process is technology readiness, IT capability level, compatibility, and technology complexity.

Organizational context includes information about the company's internal characteristics, resources, and social networks that can influence technology adoption, such as top management support factors and employee capabilities. Environmental context refers to external factors that are beyond the company's control, including regulatory aspects, competitive pressures, technology availability, and market needs.

Serialization Implementation

Badan Pengawasan Obat dan Makanan – BPOM (Indonesian Food and Drug Administration) has issued regulations regarding the serialization of drug and food products in Indonesia, namely BPOM Regulation No. 22 of 2022 concerning the Implementation of 2D Barcodes in Drug and Food Control, which has been effective since November 5, 2022. This regulation regulates the implementation of a track-and-trace serialization system for drug products in Indonesia, including the technical requirements and procedures that must be met by the pharmaceutical industry and distributors. The industry is given the opportunity to make adjustments to fully implement this system within one year (BPOM, 2022).

Track and Trace is the process of tracking and tracing a product through the entire supply chain by recording certain information that allows verification of its history, location, or application. This capability includes both tracking products from source to destination (tracking) and identifying the source of products that have arrived at their destination (tracing).

In its policy document, namely the Policy Paper on Traceability of Medical Products, WHO provides some guidelines that pharmaceutical manufacturers must follow regarding traceability systems that should be applied at all stages of the production, distribution, and supply chain of pharmaceutical products. Manufacturers should implement a unique identification system on their products that can be used to trace the product from source to final destination. Manufacturers should implement a unique identification system on their products that can be used to trace the product from source to final destination. Manufacturers must also be able to provide the data needed to track products quickly and efficiently. WHO also recommends that manufacturers use a global system of standards developed by organizations such as GS1 to ensure the compatibility and interoperability of traceability systems.

Company Performance

Implementation strategies applied by companies can be in the form of competitive steps and business approaches used by company leaders to make businesses grow, attract and provide customer satisfaction, compete successfully, run operations, and achieve targeted company performance levels (Thompson et al., 2007). Therefore, strategic management needs to consider environmental factors, formulate strategies, implement and monitor strategies, and evaluate the implementation process to ensure the achievement of long-term organizational goals that are effective and efficient. Company performance is an index that measures the company's ability to provide value in terms of customer satisfaction, increase in market share, company cash flow, production costs, and productivity growth. Productivity and efficiency are overall descriptions related to company performance.Productivity is the ratio between input and output relations from production activities, including labor, capital, or other resources. While efficiency is a picture of the company's ability to get the maximum output from the total input provided, productivity is a measure of the efficiency of a company's production process (Coelli, Rao, O'Donnell, & Battese, 2005).

A company was able to deploy relevant methods and technologies. The operation went off without any difficulties and with as few obstacles and issues as possible. Employee morale and happiness were high. Improving a firm's efficiency was crucial to strategic management procedures that influenced an organization's aims (Venkatraman, 1991). If productivity fails to grow significantly, then the company's profit potential will be limited.

Conceptual Framework

Figure 1 depicts the relationship between technology, organization and environment as independent variables, with the implementation of the serialization system as the intervening variable, and company performance/productivity as the dependent variable.

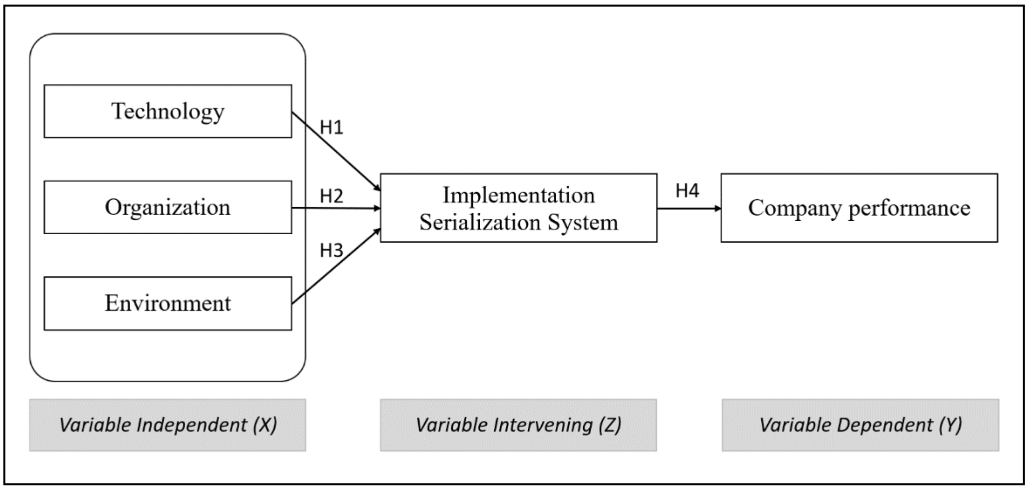

Figure 1. Research conceptual framework

Research Methodology

Based on the literature review and problem, this research raises the following questions: (i) the influence of technology on implementation of serialization system; (ii) the influence of organization on implementation of serialization system; (iii) the influence of environmental on implementation of serialization system and (iv) the effect of implementation of serialization system on company performance.

This present study used quantitative research approaches with descriptive and verification case studies. The research was conducted in May – June 2023 at one of the pharmaceutical SOEs, PT Bio Farma, by distributing questionnaires to those directly involved in the implementation of the serialization system. The number of samples is calculated using the Slovin method and the "rule of 10" based on the ratio of sampling units based on the number of non-dependent variables. Where there are nine parts to the dependent variable question, so the number of samples cannot be less than 90 respondents. The variables are as follows: technology readiness (X1.1), technology compatibility (X1.2), technological complexity (X1.3), cost (X1.4), employee capability (X2.1), management support (X2. 2), competitive pressure (X3.1), market uncertainty (X3.2), and technology adaptation (Z).

The instrument used to collect data was a questionnaire which was divided into five parts: (1) ten questions on information about technological, (2) six questions on information about organizational, (3)seven questions on information about environmental contexts, (4) two questions on implementation of serialization system, and (5) four questions on performance results of an organization. All the questions were asked on a 5-point Likert scale.

The questionnaire was validated by SPSS using Pearson Product Moment with acceptance coefficient of higher than 0.3. From the analysis it was found that the validity rate in the questionnaire passed the minimum required criteria, which was between 0.634-0.936. Cronbach's alpha coefficient was calculated with an acceptable reliability coefficient of higher than 0.7 for a reliable questionnaire. From the analysis, it was found that the reliability rates of all five variables in the questionnaire passed the minimum required criteria, which was between 0.769-0.874. The data were analyzed using descriptive analysis. Structural equation modelling (PLS-SEM type) was used to analyze the data related to the confirmation of the hypothesis.

Results And Discussion

General Data Analysis

From general data analysis, for education level, the majority of the respondents are employees with high school education—as many as 158 people, or 65.83%. The characteristics of work ties show that the majority of respondents answered outsourcing, namely 145 people, or 60.42%. As for the characteristics of the position, it shows that the majority of respondents answered the executor, namely 222 people, or 92.50%. For the characteristics of the working period, it shows that the majority of respondents answered more than 10 years, namely as many as 92 people, or 38.33%. As well as the characteristics of working years in the current position, it shows that the majority of respondents answered 2–5 years, namely 82 people, or 34.17%.

Results of Structural Equation Modeling

In the initial reliability test, it is known that there are latent constructs that have a Cronbach's alpha value of less than 0.7, namely in the latent variables dimensions X1.3, X2.1, and Y2. This indicates that the latent construct has poor reliability. Then, the variables that were observed to be invalid were eliminated from the initial SEM-PLS model, then re-tested with the final test results as follows:

Table 1. Loading Factor

Construct	*Loading Factor*	Criteria (*Loading Factor* ≥ 0,7)
X1.1.1 ← X1.1	0,916	Valid
X1.1.2 ← X1.1	0,914	Valid
X1.2.1 ← X1.2	0,873	Valid
X1.2.2 ← X1.2	0,894	Valid
X1.2.3 ← X1.2	0,868	Valid
X1.4.1 ← X1.4	0,894	Valid
X1.4.2 ← X1.4	0,890	Valid
X1.4.3 ← X1.4	0,743	Valid
X2.2.1 ← Organization (X2)	0,817	Valid
X2.2.2 ← Organization (X2)	0,825	Valid
X2.2.3 ← Organization (X2)	0,758	Valid
X2.2.4 ← Organization (X2)	0,861	Valid
X3.1.1 ← Environmental (X3)	0,671	Valid
X3.1.2 ← Environmental (X3)	0,711	Valid
X3.1.3 ← X3.1	0,876	Valid
X3.1.4 ← X3.1	0,853	Valid
X3.1.5 ← X3.1	0,891	Valid
X3.2.1 ← X3.2	0,894	Valid
X3.2.2 ← X3.2	0,864	Valid
Y1.1 ← Company Performance (Y)	0,874	Valid
Y1.2 ← Company Performance (Y)	0,912	Valid
Z1 ← Implementation Serialization System (Z)	0,931	Valid
Z2 ← Implementation Serialization System (Z)	0,939	Valid

Table 2. Cronbach's Alpha and Composite Reliability

Latent	*Cronbach's Alpha*	*Composite Reliability*
X1.1	0,806	0,912
X1.2	0,852	0,910
X1.4	0,796	0,882
X3.1	0,844	0,906
X3.2	0,707	0,872

Latent	*Cronbach's Alpha*	*Composite Reliability*
Technology (X1)	0,873	0,900
Organization (X2)	0,834	0,889
Environmental (X3)	0,850	0,886
Implementation Serialization System (Z)	0,857	0,933
Company Performance (Y)	0,748	0,887

Table 3. Average Variance Extracted

Latent	*Average Variance Extracted* (AVE)	Criteria ($AVE \geq 0.5$)
X1.1	0,838	Valid
X1.2	0,771	Valid
X1.4	0,714	Valid
X3.1	0,762	Valid
X3.2	0,773	Valid
Teknologi (X1)	0,532	Valid
Organisasi (X2)	0,666	Valid
Lingkungan (X3)	0,527	Valid
Implementasi Sistem Serialisasi (Z)	0,875	Valid
Performa Perusahaan (Y)	0,797	Valid

Tabel 4. Discriminant Cross Loading

	X1.1	X1.2	X1.4	X2	X3.1	X3.2	Z	Y
X1.1.1	**0,916**	0,604	0,466	0,604	0,255	0,545	0,509	0,454
X1.1.2	**0,914**	0,627	0,426	0,582	0,288	0,440	0,411	0,464
X1.2.1	0,633	**0,873**	0,411	0,566	0,397	0,476	0,408	0,561
X1.2.2	0,567	**0,894**	0,385	0,535	0,320	0,452	0,473	0,540
X1.2.3	0,572	**0,868**	0,415	0,557	0,412	0,518	0,496	0,618
X1.4.1	0,432	0,385	**0,894**	0,457	0,438	0,390	0,449	0,389
X1.4.2	0,390	0,425	**0,890**	0,440	0,481	0,385	0,455	0,428
X1.4.3	0,416	0,354	**0,743**	0,440	0,366	0,384	0,426	0,285
X2.2.1	0,468	0,479	0,456	**0,817**	0,362	0,520	0,523	0,494
X2.2.2	0,500	0,446	0,433	**0,825**	0,297	0,575	0,552	0,511
X2.2.3	0,565	0,482	0,375	**0,758**	0,332	0,516	0,405	0,400
X2.2.4	0,592	0,633	0,451	**0,861**	0,360	0,581	0,629	0,572
X3.1.1	0,507	0,503	0,375	0,637	**0,399**	0,548	0,479	0,503
X3.1.3	0,254	0,416	0,470	0,374	**0,876**	0,456	0,367	0,593
X3.1.4	0,228	0,362	0,406	0,327	**0,853**	0,414	0,301	0,483
X3.1.5	0,293	0,345	0,455	0,378	**0,891**	0,455	0,298	0,502

	X1.1	X1.2	X1.4	X2	X3.1	X3.2	Z	Y
X3.2.1	0,468	0,502	0,384	0,560	0,528	**0,894**	0,504	0,575
X3.2.2	0,481	0,463	0,422	0,625	0,353	**0,864**	0,658	0,470
Z1	0,437	0,483	0,493	0,598	0,326	0,606	**0,931**	0,445
Z2	0,502	0,492	0,488	0,631	0,364	0,620	**0,939**	0,478
Y1.1	0,453	0,623	0,436	0,502	0,591	0,467	0,403	**0,874**
Y1.2	0,445	0,551	0,354	0,589	0,497	0,591	0,475	**0,912**

Factor loading analysis showed that every latent variable had composite reliability of more than 0.7 and Cronbach's alpha of more than 0.7. It could then be concluded that all latent variables in the model were reliable. In addition, convergent validity showed that every latent variable had AVE of more than 0.50. Therefore, it could be concluded that there was a related validity among manifest variables under the same latent variables in every latent variable of the model, and that all manifest variables in the model were reliable, as presented in table 1 – 3.

From discriminant validity analysis, it was found that the square root of AVE of each latent variable was more than the correlation between those latent variables and other variables in the model. It was then concluded that all latent variables of the model had discriminant validity and were measured with accurate manifest variables, as shown in table 4.

Hypothesis Analysis and Discussion

In this study, the hypothesis was tested by calculating the path coefficient, t-table values, and p-value to determine significance and predictions in hypothesis testing (Kock, N., 2016). The t-table values can be seen in the following table:

Tabel 5. t-table value

	One tailed
t-tabel	1,64

At the 95% confidence level (5% alpha), one-tailed, the t-table values are obtained as follows:

1. If the t-statistic value is > 1.64 (used for direct influence), then H0 is rejected and H1 is accepted.
2. If the t-statistic value is <1.64 (used for direct influence), then H0 is accepted and H1 is rejected.

The hypothesis test was carried out by the bootstrapping method using SmartPLS software, and the results obtained are as follows:

Influence of Technology on Serialization System Implementation

Table 6 shows that the Original Sample (O) value is 0.184, indicating that the direction of the influence of technology on the implementation of the serialization system is positive or unidirectional, meaning that the better the technology, the better the implementation of the serialization system. The influence of technology on the implementation of the serialization system is significant, with a t-statistic value of 2.013 greater than t table or 2.013 > 1.64 and a p-value of 0.045 less than alpha 5% (0.05). Thus, $H_{1.1}$ is accepted, meaning that technology has a positive and significant influence on the implementation of the serialization system.

Tabel 6. Path-Coefficient and t-table: Influence of Technology on Serialization System Implementation

Effect	***Original Sample* (O)**	**t-Statistic**	***p-value***	**Conclusion**
Technology on Serialization System Implementation	0,184	2,013	0,045	$H_{0.1}$ Rejected

Influence of Organization on Serialization System Implementation

Table 7 shows that the Original Sample (O) value is 0.320, indicating that the direction of the influence of organizational on the implementation of the serialization system is positive or unidirectional, meaning that the better the organizational context, the better the implementation of the serialization system. The influence of organizational on the implementation of the serialization system is significant, with a t-statistic value of 4.180 greater than t table or 4.180 > 1.64 and a p-value of 0.000 less than alpha 5% (0.05). Thus, $H_{1.2}$ is accepted, meaning that organization has a positive and significant influence on the implementation of the serialization system.

Tabel 7. Path-Coefficient and t-table: Influence of Organizational on Serialization System Implementation

Effect	***Original Sample* (O)**	**t-Statistic**	***p-value***	**Conclusion**
Organizational on Serialization System Implementation	0,320	4,180	0,000	$H_{0.2}$ Rejected

Influence of Environment on Serialization System Implementation

Table 8 shows that the Original Sample (O) value is 0.294, indicating that the direction of the influence of environment on the implementation of the serialization system is positive or unidirectional, meaning that the better the environment, the better the implementation of the serialization system. The influence of environment on the implementation of the serialization system is significant, with a t-statistic value of 4.103 greater than t table or 4.103 > 1.64 and a p-value of 0.000 less than alpha 5% (0.05). Thus, $H_{1.3}$ is accepted, meaning that environment has a positive and significant influence on the implementation of the serialization system.

Tabel 8. Path-Coefficient and t-table: Influence of Environment on Serialization System Implementation

Effect	***Original Sample* (O)**	**t-Statistic**	***p-value***	**Conclusion**

Environment on Serialization System Implementation	0,294	4,103	0,000	$H_{0.3}$ Rejected

Influence of Serialization System Implementation on Company Performance

Table 9 shows that the Original Sample (O) value is 0.494, indicating that the direction of the influence of the implementation of the serialization system on company performance is positive or unidirectional, meaning that the better the the implementation of the serialization system, the better the company performance. The influence the implementation of the serialization system on company performance is significant, with a t-statistic value of 7.953 greater than t table or 7.953 > 1.64 and a p-value of 0.000 less than alpha 5% (0.05). Thus, $H_{1.4}$ is accepted, meaning that the implementation of the serialization system has a positive and significant influence on the company performance.

Tabel 8. Path-Coefficient and t-table: Influence of the implementation of the serialization system on company performance

Effect	***Original Sample* (O)**	**t-Statistic**	***p-value***	**Conclusion**
Implementation of the serialization system on company performance	0,494	7,953	0,000	$H_{0.4}$ Rejected

Based on the results of testing and analysis of the measurement model and structural model, it can be seen that the model meets the requirements. Thus, the model used in the research represents the research data. The results of the hypothesis testing show that all hypotheses are proven to have a positive and significant relationship in that TOE influences the implementation of the serialization system at PT Bio Farma, which affects company performance.

The technological context contributes positively, so companies must consider the availability of technology so that the implementation of the serialization system will also be better. In this study, technology includes adequate technology, even though it has higher complexity and a high cost, but the technology should be compatible with the expected system implementation. In the organizational context, the factors that must be considered by the company are the need for management support and the need for increased employee capabilities so that they are adequate for the expected implementation of the serialization system. In the environmental context, the existence of competitive pressures and market uncertainty needs to be properly considered by the company. Implementation of a serialization system helps companies face challenges in the market and allows them to cope with market uncertainties (Deelert et al., 2021). This has a positive influence on company performance in terms of customer and employee satisfaction.

Conclusion And Recommendation

Conclusion

This study concluded that the technological context, organizational context, and environmental context influence the performance of the pharmaceutical industry namely PT Bio Farma through serialization system implementation. If Bio Farma wants to succeed in implementing serialization systems to lead to better company performance, the factors to keep in mind are as follows: 1) technology readiness, 2) technology compatibility, 3) the complexity of the technology, 4) cost, 5) employee capability, 6) management support, 7) competitive pressure, 8) market uncertainty, and 9) technology adaptation.

The consideration of these nine factors by the organization would help the operation of the serialization system be successful, which would lead to efficient performance, create opportunities, and gain competitive advantages.

Recommendation

This research is expected to help managers and decision-makers in a company by providing recommendations, considerations, and references dalam melakukan adopsi dan implementasi teknologi sistem serialisasi untuk menciptakan keuntungan dalam kompetisi bisnis dan meningkatkan performa perusahaan. Researchers in the future should consider using mixed methodologies research, which combines quantitative and qualitative research. The research could be conducted primarily using quantitative approaches, with qualitative methods used to collect more thorough and in-depth data.

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