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DEVELOPING STRATEGIES TO IMPROVE PRODUCTION DOCUMENTATION QUALITY IN THE PHARMACEUTICAL INDUSTRY: A CASE STUDY OF PT. XYZ

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ABSTRACT

In the pharmaceutical industry, documentation quality in toll manufacturing products is a key factor in maintaining customer satisfaction and trust. The decline in customer satisfaction in toll manufacturing services of PT XYZ is reflected in the decrease of the Customer Satisfaction Index (CSI) from 2024 to 2025, as well as the high gap in the attributes of accuracy and completeness of batch record documentation, where customer expectations reached 100 while the performance was only 72. This study aims to identify the root causes of the high gap in the attributes of accuracy and completeness in filling out batch records, analyze internal and external factors that influence it, formulate alternative improvement strategies through SWOT analysis, and determine strategy priorities based on Quantitative Strategic Planning Matrix (QSPM) analysis. The results indicate that the main problems stem from human resources, methods, and systems, including high workload, differences in understanding, and a still paper-based documentation system. The QSPM results were used to determine priority strategies, including optimizing training programs based on audit findings, implementing an integrated documentation system, and standardizing training programs. These strategies are expected to improve the accuracy and completeness of batch records and enhance customer satisfaction.

Keywords: Customer Satisfaction Index (CSI), Batch record, Toll Manufacturing, Fishbone Diagram, SWOT, QSPM

1 INTRODUCTION

The pharmaceutical industry has strict regulations for its production processes because the products are directly related to public health. Each process must be thoroughly documented and accurately follow the Good Manufacturing Practice (GMP) standards. PT XYZ, as one of Indonesia's pharmaceutical companies, implements a toll manufacturing system in both toll-in and toll-out forms. The company must provide services that meet customer expectations. Satisfied

customers tend to be loyal, which contributes to repeat transactions and becomes a crucial factor in a competitive market with changing customer preferences [1].

The Customer Satisfaction Index (CSI) is one method used to measure customer satisfaction levels. CSI provides clear data on customer satisfaction, allowing periodic evaluations to identify areas for improvement and enhance services customers perceive as adding value [2]. Customer satisfaction depends on customers' perception of how well a product or service meets their expectations [3]. If expectations are met or exceeded, customer satisfaction is achieved. Gap analysis is a method used to evaluate performance and determine the current system's performance level against a standard system used as a reference [4].

Based on the 2024 and 2025 CSI data for PT XYZ, customer satisfaction with the toll manufacturing services has declined. In 2024, the CSI value was 82.2, while in 2025, the CSI was 81.6. Focusing on quality, ten attributes are assessed, and the gap between importance and performance is shown in Figure 1. In 2025, the largest gap is for the accuracy and completeness of filling out the batch record, with a gap value of 28. This value represents the difference between the expected level from customers (100) and the perceived service level by customers (72). This value is quite high, and this attribute also had a large gap last year. Additionally, compared to 2024, the gap in this attribute appears to have increased. This indicates that the improvements made in the previous year were not effective or perhaps not implemented at all, leading to customer dissatisfaction with this attribute. Therefore, enhancing services in the priority attributes for improvement is necessary to reduce the potential gap between customer perception and expectations [2].

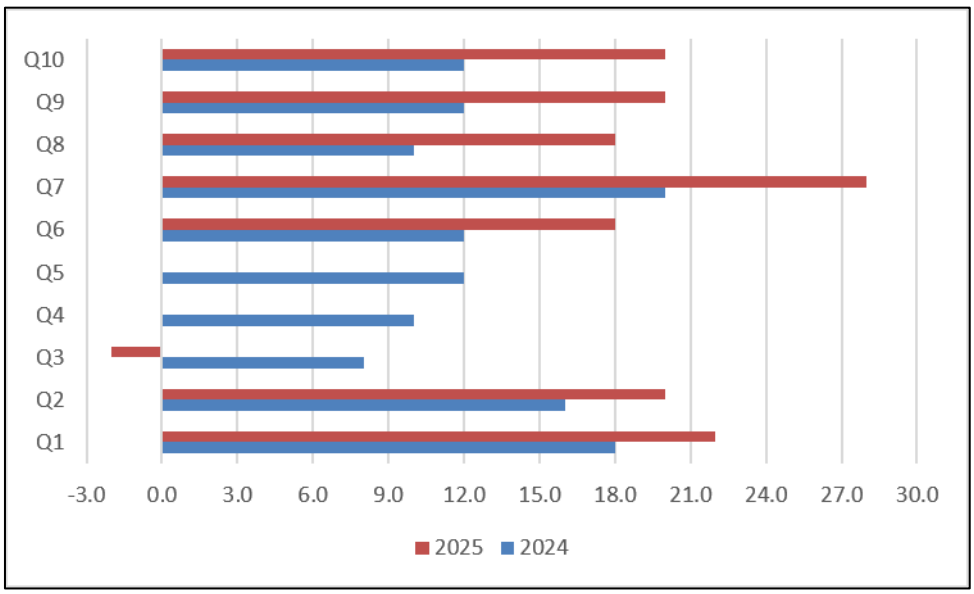


Figure 1: Gap Analysis Result for Toll in Manufacturing in 2024 and 2025

In GMP 2024, good documentation is essential to quality control. Batch records are essential documents that need to be accurately and thoroughly completed to accurately reflect the actual conditions. This issue encourages the need for in-depth analysis and the formulation of strategies to decrease the gap. This study aims to identify the root causes of the large gap in batch record accuracy and completeness, analyze the internal and external factors that influence it, and formulate alternative improvement strategies using SWOT and QSPM analyses. The SWOT analysis was used to formulate strategic alternatives based on the identified internal strengths and weaknesses and external opportunities and threats [5]. The study then evaluated these strategic alternatives using the QSPM [5]. Each factor was assigned an attractiveness score reflecting each strategy's relative attractiveness in responding to the factor. The Total Attractiveness Score (TAS) was then calculated to determine the priority strategy.

2 RESEARCH METHOD

This research was conducted during January–February 2026. The approach used was a combination of qualitative and quantitative methods to analyze issues in the process of filling out batch records for toll manufacturing products (toll in). Data collection was carried out through interviews, direct observation, and questionnaires distributed to parties involved in the production and documentation processes. Qualitative data were collected through interviews and discussions with the Toll out Toll in (TOTI) manager and pertinent expert personnel, including one individual from the raw material warehouse, four individuals from the production department, one from Quality Control, and one from Quality Assurance. Quantitative data were obtained by distributing IFE-EFE questionnaires to representatives from eight related departments, as well as QSPM questionnaires completed by the General Manager of PPIC.

The research process begins by identifying the problem using the fishbone diagram method to determine the main root causes. Subsequently, an internal factor analysis is undertaken employing the Porter Value Chain [6], while an external factor analysis is carried out utilizing PESTEL analysis [7]. The insights derived from these analyses are then used to develop the internal factor evaluation (IFE) and external factor evaluation (EFE) matrices, which serve to identify the organization's strengths, weaknesses, opportunities, and threats. This is followed by strategy formulation through the application of SWOT analysis. The final stage used the QSPM method to determine the most effective and objective strategy priorities based on the attractiveness score of each alternative strategy. The results of this analysis serve as the basis for system improvement recommendations to enhance the accuracy and completeness of batch record filling and increase customer satisfaction.

3 RESULT AND ANALYSIS

3.1 Root Cause Analysis

The fishbone diagram analysis was conducted to identify the root causes of incomplete and incorrect batch record entries at PT XYZ, as shown in Figure 2. Based on the fishbone diagram, the researchers found that the review process is layered, which extends the lead time, and the SOP has not been standardized across departments. The system remains paper-based and lacks integration, leading to less accurate document tracking. Variations in batch record formats exist between internal and toll givers, with some products still lacking available formats. Additionally, there are no shared KPIs or specific error rate targets for the toll-in process. Coordination between departments is slow, and management support for toll manufacturing remains low.

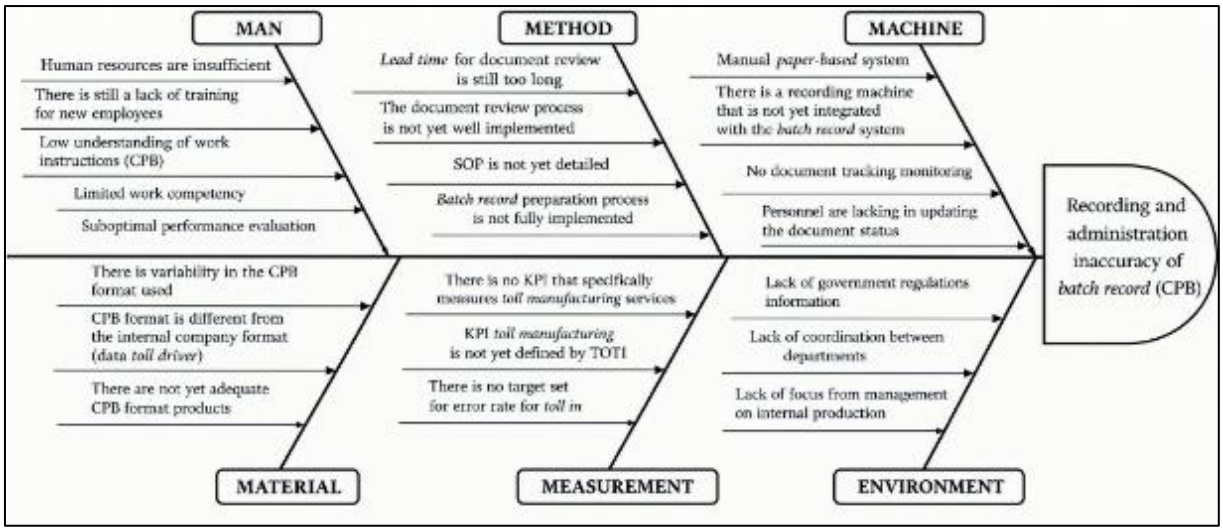


Figure 2: Fishbone Diagram

The fishbone diagram analysis shows that the main causes of incomplete and inaccurate batch record filling stem from six main factors: man, method, machine, material, measurement, and environment. The dominant factors include high personnel workload, differences in understanding documentation standards, layered review processes, a still paper-based documentation system, variability in batch record formats, the absence of cross-department KPIs, and slow coordination between departments.

3.2 IFE, EFE, and IE Matrix

In the process of documenting batch records for toll-in products at PT XYZ, there are several strengths, weaknesses, opportunities, and threats. Furthermore, based on these strengths, weaknesses, opportunities, and threats, IFE and EFE can be developed, as shown in Table 1 and Table 2. Based on the analysis of internal and external environments using the IFE and EFE matrices, a score of 3.2 is obtained for the IFE matrix. This value indicates that the company has a good ability to utilize its strengths to support batch record documentation management. The company's main strengths lie in the existence of GMP-based batch record filling SOPs, a Quality Assurance team responsible for document inspection, and the implementation of documentation recording at each production process. Meanwhile, the EFE matrix score of 2.88 shows that the company has a fairly good ability to capitalize on opportunities and face threats from the external environment. However, the company still needs to improve its response to some opportunities and threats to better support performance enhancement.

Table 1: Internal Factor Evaluation (IFE)

Internal Factor	Weight	Rating	Score
Strength			
Management support to improve the quality of the company	0.092	3.0	0.276
Having an SOP for filling out batch records based on GMP	0.123	4.0	0.490
Availability of good document filing training and training work program	0.080	2.6	0.211
There is a Quality Assurance (QA) team responsible for document inspection	0.123	4.0	0.490
In every production process carried out, batch records, logbooks, or other documentation are always recorded.	0.123	4.0	0.490
The batch record filling has been double-checked at each stage of the production process.	0.119	3.9	0.460
Total	0.659	21.5	2.4
Weakness			
There is still variability in the batch record format.	0.073	2.4	0.173
The difference in understanding and implementation of batch record filling standards among personnel (subjectivity) results in incomplete entries.	0.065	2.1	0.138
There is no specific person responsible for handling toll-in products at each stage of production.	0.073	2.4	0.173
Training related to documentation has not been conducted routinely but rather upon request.	0.073	2.4	0.173
The multi-level review process extends lead times, making real-time execution difficult.	0.069	2.3	0.155
Integration of production support equipment and facilities has not been optimized for CPB data entry.	0.061	2.0	0.123
Total	0.341	11.1	0.8
Cumulative Total	1.00	32.6	3.2

Table 2: External Factor Evaluation (EFE)

External Factor	Weight	Rating	Score
Opportunity			
The existence of audits by regulators as a learning process and system improvement to align with the latest regulatory developments.	0.21	3.00	0.63
Availability of industry best practices in pharmaceutical industry documentation management for batch records.	0.21	3.00	0.63
Total	0.58	8.25	1.62
Threat			
1. Variability in the competency level of contract workers involved in the production process participating in filling out batch records	0.24	3.38	0.80
The toll giver company has its own batch record format that is different from the format used by the company.	0.24	3.38	0.80

The existence of a difference in perception of the batch record review from PT XYZ and the toll giver party.	0.18	2.63	0.48
The process of reviewing and returning documents delays the product release time.	0.22	3.13	0.69
The decline in customer satisfaction levels and repurchase intention from customers due to documentation issues.	0.20	2.88	0.58
Total	0.42	6.00	1.27
Cumulative Total	1.00	14.25	2.88

Figure 3 is the position of PT XYZ based on the IFE and EFE scores. Based on these two values, the position of the pharmaceutical industry is in quadrant IV. This position indicates that the company requires strategies for more effective growth and development. At this stage, the company may implement intensive, integrative, and concentration strategies [5].

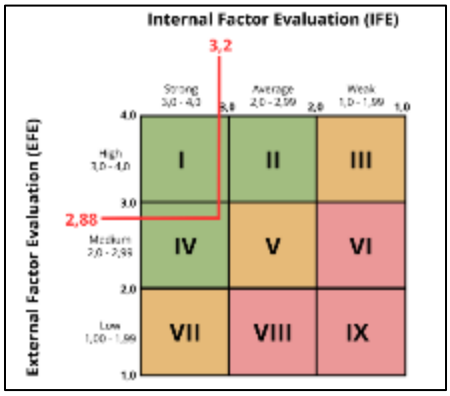


Figure 3: IE Matrix

3.3 SWOT Analysis

SWOT analysis provides a framework for analyzing strengths and weaknesses (internal factors) and opportunities and threats (external factors), assuming that a company must align internal activities with external realities to achieve objectives effectively [8]. At this stage, the team develops strategies for the batch record documentation process for toll-in products. The proposed strategies are obtained from brainstorming sessions with related divisions, including production, raw material warehouse, Quality Assurance, Quality Control, and the PPIC team. The proposed strategies are based on a combination of strengths (S) and weaknesses (W), opportunities (O), and threats (T), as follows.

- Implementation of integrated digital batch record filling across processes with review systems from Quality Assurance and in accordance with SOP formats (S2, S4, O1).
- Optimize the existing procedure documentation training program by utilizing regulator audit findings as learning material for continuous improvement of the batch record documentation system (S6, O2).
- Adopt best practices from other pharmaceutical industry players in managing batch records by referring to standard procedur-based SOPs and ongoing QA supervision (S2, S4, O3).
- Maximize the function of Quality Assurance and the double-check system for batch records through centralized communication of document changes to prevent audit findings that threaten company stability (S4, S5, T6).
- Optimize the standardized batch record format and SOP to prevent product release delays and minimize risks of decreased customer satisfaction (S2, S4, T1, T5).
- Align batch record SOPs with toll givers through cross-functional coordination supported by internal SOPs based on standard procedure to minimize perception differences and audit finding risks (S1, S3, T3, T4).
- Develop and implement a scheduled and standardized documentation training program based on regulator audit findings and best practices to improve personnel understanding of batch record filling standards (W1, W, O2, O3).
- Digital batch record realization to accelerate lead time for batch record recording processes and minimize errors (W4, O1).
- Prepare technical guidelines and standard checklists for batch record filling integrated with documentation systems to improve consistency and reduce administrative errors (W1, W2, O1).

- Enhance facility and supporting documentation systems integration to reduce dependence on contract workers with varying competencies (W5, T1).
- Simplify checking workflows and assign specific responsible persons for toll-in products to reduce the risk of excessively long batch record filling lead times, which impact customer satisfaction (W2, W4, T5).
- Improve workforce competency consistency through standardized documentation training for both contract and permanent workers to reduce recording errors, reputation issues, and audit findings (W1, W3, T5).

3.4 QSPM Analysis

The 12 formulated strategies will be prioritized using the QSPM. The QSPM is a high-level strategic management methodology used to assess potential strategies and objectively identify the optimal strategy by integrating inputs from other management techniques and straightforward calculations [9]. The strategy priorities are chosen based on the strategy with the highest TAS. TAS for each strategy is obtained from the QSPM questionnaire and the weighting results from the attribute matrices in the IFE and EFE matrices. As a result, three strategy priorities are identified as shown in Table 3.

Table 3: QSPM Strategic Priority

Criteria	TAS	Priority
Implementation of digital batch records that comply with SOP and standardized formats according to standard procedure for medicine production, and are integrated with the review system from Quality Assurance (S1, S2, S3, O1).	10.9	2
Optimize the existing standard procedure documentation training program by utilizing regulator audit findings as learning material for continuous improvement of the batch record documentation system (S6, O2).	11.1	1
Developing and implementing a scheduled and standardized documentation training program based on regulator audit findings and best practices to improve personnel's uniform understanding of batch record filling standards (W1, W, O2, O3).	10.2	3

The results of the QSPM analysis indicate three strategies with the highest scores as priorities for improvement. Applying these three strategies is expected to enhance personnel competence, speed up the documentation process, reduce human error, and improve data integrity and customer satisfaction.

3.5 Improvement Recommendation

From these three strategic priorities, appropriate improvement recommendations were then developed. Based on the QSPM analysis results, three prioritized strategies are recommended to enhance the quality of batch record documentation. The first priority is to conducting regular training sessions at least every six months, incorporating audit findings into the training content, in line with guidelines that mandate ongoing training for all staff. The training should be conducted periodically and supported by standardized modules to improve personnel understanding and consistency in filling out batch records. The second priority is to implement digitalization of batch records in accordance with SOP and integrate them with the QA review system. Implementing Electronic Batch Records (EBR) can reduce human error by 75% compared with hardcopy systems [10]. Additionally, digitalization allows for real-time data monitoring. The third strategy is to organize scheduled and standardized training programs based on audit findings and industry best practices. The implementation of ALCOA data integrity principles is also recommended to ensure data is documented accurately, traceable, and secure, thereby supporting GMP implementation and continuous improvement of documentation quality [11].

The three priority strategies have essentially been implemented by the company before, but it still haven't been carried out consistently and optimally. Digitalization of batch records has started, but manual activities and duplicated work remain. Training programs are in place, but they are only conducted upon request, not on a regularly scheduled basis.

4 CONCLUSION

The root cause of incomplete batch record filling at PT XYZ is caused by six main interconnected factors: workload and differences in understanding (man), layered review processes and non-standardized SOPs (method), use of paper-based systems (machine), variability in batch record formats (material), lack of shared KPIs (measurement), and slow coordination (environment).

PT XYZ is in the grow-and-build position (Quadrant IV of the IE Matrix), supported by an IFE score of 3.2 and an EFE score of 2.88. The company's main strengths include SOPs, the QA team, and consistent documentation. Meanwhile, the biggest threat comes from variability in contract workers' competency and differences in batch record formats with toll givers.

The results of the QSPM analysis identified three priority strategies: (1) continuous optimization of standard procedures for medicine production documentation training programs based on audit findings; (2) implementation of an integrated Electronic Batch Record (EBR) system with the QA review system; and (3) development of a structured training program based on best practices and ALCOA principles.

This research has several limitations. First, the study was conducted during a one-month internship period, so the observation of the batch record filling process could not fully cover the entire production cycle in depth. Second, the respondents were limited to internal company personnel, so the toll giver's perspective as a customer was not directly incorporated into the evaluation. Third, root cause analysis using the fishbone diagram remains qualitative and has not been validated through measuring the frequency of each causal factor. Additionally, the determination of weights and the Attractiveness Score in the QSPM analysis depends on internal expert judgment, which could introduce subjectivity. This study is also limited to strategy formulation and does not evaluate the implementation of the proposed strategies.

STATEMENTS ON COMPLIANCE WITH ETHICAL STANDARDS

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Disclosure of conflict of interest

The authors declare no conflicts of interest regarding this manuscript.

REFERENCES

[1] Curtis T, Abratt R, Rhoades DL and Dion P. (2011). Customer loyalty, repurchase and satisfaction: A meta-analytical review. Journal of Consumer Satisfaction, Dissatisfaction and Complaining Behavior, 24, 1-26.

[2] Debora F, Fasa N, Sudrajat HA and Apriliani A. (2023). Analysis of service quality on Lestari Seserahan SME customer satisfaction with the Customer Satisfaction Index (CSI) and Importance Performance Analysis (IPA) methods. Indonesian Journal of Industrial Engineering and Management, 4(1), 78-86.

[3] Yanova N. (2015). Assessment of satisfaction with the quality of education: Customer Satisfaction Index. Procedia - Social and Behavioral Sciences, 182, 566-573.

[4] Kim S and Ji Y. (2018). Gap analysis. In: Heath RL and Johansen W (Eds), The International Encyclopedia of Strategic Communication. John Wiley & Sons. DOI: 10.1002/9781119010722.iesc0079.

[5] Wahmil DS, Pramono SNW and Ulkhaq MM. (2025). Optimizing business strategy through SWOT and QSPM: A case study of CV Cita Nasional's strategic challenges. Journal of Economic Analysis, 4(3), 65-89.

[6] Porter ME. (1985). Competitive advantage: Creating and sustaining superior performance. Free Press, New York, USA.

[7] Yüksel I. (2012). Developing a multi-criteria decision making model for PESTEL analysis. International Journal of Business and Management, 7(24), 52-66.

[8] Pahl N and Richter A. (2009). SWOT analysis: Idea, methodology and a practical approach. GRIN Verlag, Munich, Germany.

[9] Zulkarnain A, Wahyuningtias D and Putranto TS. (2018). Analysis of IFE, EFE and QSPM matrix on business development strategy. IOP Conference Series: Earth and Environmental Science, 126(1), 012062.

[10] Thammarungsri S and Rungpragayphan S. (2016). Data management in herbal medicinal products manufacturing processes: Documentation, batch processing record and electronic data management. Isan Journal of Pharmaceutical Sciences, 12(2), 44-56.

[11] Leal F, Chis AE, Caton S, et al. (2021). Smart pharmaceutical manufacturing: Ensuring end-to-end traceability and data integrity in medicine production. Big Data Research, 24, 100172.