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TRANSFORMATION OF THE DRUG MONITORING SYSTEM THROUGH LEAN SIX SIGMA (LSS)

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Abstract: Drug distribution oversight in Indonesia faces recurring violations, weak regulatory enforcement, and inefficiencies in post-inspection follow-ups. This study investigates the root causes of these issues and evaluates the effectiveness of Lean Six Sigma (LSS) in improving the supervision system at the Indonesian Food and Drug Authority Regional Office in Serang. A qualitative approach using the DMAIC (Define, Measure, Analyze, Improve, Control) framework was applied to analyze inspection reports, institutional performance data (2019–2024), and in-depth interviews with key stakeholders. The findings reveal that repeated violations stem from ineffective CAPA processes, limited human resource capacity, fragmented regulations, and the absence of integrated digital systems. Implementing LSS led to faster follow-up actions, standardization of inspection procedures, and improved coordination. The study concludes that LSS can serve as a strategic method to enhance data-driven, collaborative, and risk-based drug surveillance. This research contributes to the development of digital public health supervision models and highlights the need for regulatory harmonization across institutions.

Keywords: Lean Six Sigma, Drug Supervision, CAPA, Risk-Based Inspection, Regulatory Enforcement, Digital Transformation

INTRODUCTION

The supervision of pharmaceutical distribution facilities and pharmacy service units is a vital component of the national health resilience system, as it ensures that circulating pharmaceutical products meet quality standards, are safe for use, and are therapeutically effective. Failure in supervisory functions not only increases the risk of drug misuse but also poses a broader threat to patient safety. Therefore, pharmaceutical oversight must be carried out systematically, based on risk, and capable of adapting to the dynamics of modern pharmacy service systems. In Indonesia, the responsibility for overseeing drug distribution lies with the National Agency of Drug and Food Control (BPOM) and is implemented through technical executing units such as the Balai Besar POM (BBPOM) in Serang. Despite the enactment of various regulations such as Law No. 17 of 2023 on Health, Government Regulation No. 28 of 2024, and Ministerial as well as BPOM regulations including BPOM Regulation No. 9 of 2019, the implementation on the ground continues to face structural and operational challenges [1].

Repeated violations found in pharmacies, drug stores, clinics, and pharmaceutical wholesalers (PBF), as well as the suboptimal impact of inspection follow-ups and inconsistent implementation of Corrective and Preventive Actions (CAPA), highlight the need to strengthen both organizational learning systems and policy enforcement mechanisms in pharmaceutical supervision [2]. Further challenges involve human resource constraints, lack of digital technology utilization, and limited inter-agency coordination. Many distribution facilities have not yet fully implemented digital reporting systems, while audit data are rarely used to forecast risks effectively [3]. On the other hand, the absence of pharmacists, infrequent re-training of pharmacists and pharmaceutical technicians, and high inspector workloads have hindered the implementation of evidence-based and preventive supervision.

To address these issues, a quality management approach is needed, one that not only emphasizes administrative compliance but also focuses on process efficiency and the reduction of unnecessary variation. Lean Six Sigma (LSS) is a proven methodology that systematically identifies root causes and improves process performance through the stages of Define, Measure, Analyze, Improve, and Control (DMAIC) [4]. LSS is not only relevant in manufacturing sectors but is increasingly adopted in public service and healthcare institutions as a tool for structural reform oriented toward results [5].

Empirical studies have shown that applying LSS in public service contexts can reduce lead time, enhance the effectiveness of follow-up actions, and strengthen internal accountability [3]. The method also promotes a data-driven and collaborative work culture, which is essential for complex pharmaceutical supervision systems involving multiple stakeholders. Within the national policy framework, the approach aligns with Presidential Instruction of the Republic of Indonesia No. 3 of 2017 concerning the Improvement of Drug and Food Supervision Effectiveness, which underscores the importance of systemic collaboration and efficiency in governance, especially in the field of pharmaceutical and food control [4].

Given this background, this study aims to identify the root causes of recurring findings in the supervision of drug distribution, analyze the effectiveness of Lean Six Sigma in improving the supervisory processes carried out by BBPOM, and formulate a more efficient, collaborative, and digitally integrated risk-based supervision strategy. By doing so, the research seeks to contribute to strengthening pharmaceutical governance through a structured and data-driven approach that is aligned with national health policy goals.

2. LITERATURE REVIEW

2.1 Drug Distribution Supervision

Drug distribution is an essential component of the national healthcare system, ensuring that medicines delivered to the public meet established standards of safety, efficacy, and quality. In the context of regulatory oversight, distribution represents a critical control point due to the large number of facilities and stakeholders involved, including pharmaceutical wholesalers (Pedagang Besar Farmasi/PBF), government pharmaceutical installations (Instalasi Farmasi Pemerintah/IFP), pharmacies, clinics, hospitals, public health centers, and drugstores. As such, the regulatory system must be designed in a systematic and risk-based manner to effectively detect, prevent, and address violations [1].

In Indonesia, the National Agency of Drug and Food Control (BPOM), through its technical implementing units such as BBPOM in Serang, holds the responsibility for supervising drug distribution and pharmacy service facilities. BPOM Regulation No. 9 of 2019 outlines the procedures and approaches for facility-level risk-based inspections [2]. However, implementation on the ground still reveals various weaknesses, including repeated violations, weak execution of Corrective and Preventive Actions (CAPA), and the lack of consolidated data to support more decisive follow-up actions. These issues indicate that current supervision practices remain reactive in nature and have yet to fully embrace predictive analytics and the principles of continuous improvement.

2.2 Corrective Action and Preventive Action (CAPA)

Another critical element in ensuring effective pharmaceutical oversight is the implementation of Corrective and Preventive Actions (CAPA). CAPA is a remedial mechanism aimed at identifying deviations, tracing their root causes, and formulating preventive measures to avoid recurrence. In the context of drug distribution and pharmaceutical services supervision, CAPA should serve as a bridge between audit findings and the continuous improvement of quality management systems [3]. However, in practice, CAPA is often reduced to a purely administrative exercise, lacking field-based evidence and failing to allow for thorough verification during follow-up inspections [4].

One major reason for the ineffectiveness of CAPA lies in its development process, which frequently overlooks the application of Root Cause Analysis (RCA). In addition, there is often insufficient commitment from pharmacists, pharmaceutical technicians, and business actors to implement preventive measures consistently. As emphasized by Sonhaji et al., a CAPA process that is not grounded in a proper understanding of the root cause tends to produce superficial actions that yield minimal impact [5]. These challenges suggest the need for a stronger integration of evidence-based methodologies and leadership accountability in CAPA implementation within pharmaceutical regulation.

2.3 Lean Six Sigma in Public Service Supervision

Lean Six Sigma (LSS) is a quality management approach that integrates the principles of Lean, which focuses on process efficiency and waste reduction, with Six Sigma, which emphasizes minimizing variation and defects. These two methodologies are combined into a structured framework known as DMAIC, which stands for Define, Measure, Analyze, Improve, and Control [6]. Although LSS originated in the manufacturing industry, it has been widely adapted for use in the public sector and healthcare services [7].

LSS has proven effective in identifying process bottlenecks, reducing lead times, and improving operational efficiency without compromising quality [8]. In the context of public sector oversight, applying LSS can enhance audit procedures, expedite follow-up actions, and increase institutional accountability. According to Antony, LSS is particularly relevant to the public sector because it helps bridge the gap between regulatory frameworks and practical implementation in the field [9].

2.4 Digital Transformation and Data-Driven Surveillance

Digital transformation in pharmaceutical supervision involves the utilization of technology to automate reporting, map risks, and support data-driven decision-making. Internal information systems such as the Integrated Reporting Information System (Sistem Pelaporan Informasi Terpadu), along with external systems like SMARTPOM, have been developed to support BPOM's digital oversight initiatives. However, challenges remain regarding inter-agency integration and the overall effectiveness of these systems [10]. Limited system interoperability continues to result in repetitive data entry, inefficient data processing, and inadequate data sharing across sectors.

Sharma emphasizes that the success of digital transformation in the public sector depends heavily on interoperable data architecture, responsive visual dashboards, and cross-institutional collaboration [11]. Therefore, digitalization of supervision should not merely be seen as a reporting mechanism but must be designed as an analytical platform capable of detecting process deviations in real time.

2.5 Research Gaps

Previous studies on Lean Six Sigma (LSS) in the public sector have generally focused on hospitals, tax services, and licensing processes. In contrast, the application of LSS within the context of drug distribution supervision and pharmaceutical service oversight remains relatively unexplored, particularly within the framework of Indonesia’s governmental system. The absence of empirical research on the integration of CAPA, digital systems, and inter-agency coordination within the LSS framework highlights a significant gap in the existing literature that this study seeks to address.

3. RESEARCH METHODOLOGY

3.1 Pendekatan dan Desain Penelitian

This study employs a descriptive qualitative approach using the Lean Six Sigma (LSS) framework, specifically the DMAIC model, which consists of the phases Define, Measure, Analyze, Improve, and Control. This approach was selected for its capacity to reveal in-depth insights into the processes and dynamics of drug distribution supervision, including structural weaknesses, process variations, and opportunities for root cause–based improvement.

The research design is not only intended to describe the current supervisory conditions but also to map process-related issues, identify waste and defects, and formulate practical, systemic interventions applicable within the context of public oversight institutions. As such, this method provides the flexibility needed to explore complex, multidimensional problems, such as pharmaceutical supervision, which involves regulatory compliance, human resources, technological infrastructure, and intersectoral coordination [1].

3.2 Unit of Analysis and Research Location

The unit of analysis in this study is the process of drug distribution and pharmaceutical service supervision conducted by the BBPOM (Balai Besar Pengawas Obat dan Makanan) in Serang. This includes inspection planning, on-site inspection implementation, the development of follow-up actions, and the evaluation of CAPA until closure. BBPOM Serang was selected as the research locus due to its strategic position and the complex challenges it faces in overseeing pharmaceutical distribution in an area that serves as a buffer zone for the capital city and a transit route connecting provinces and islands.

The high distribution mobility in Banten Province elevates the risk of regulatory violations, thus requiring a responsive and efficient supervisory system. With ISO 9001:2015 certification for quality management and ISO 37001:2016 certification for anti-bribery management, BBPOM Serang has a solid foundation in quality and integrity to support the consistent and sustainable implementation of Lean Six Sigma.

3.3 Data Collection Technique

Data was obtained through three main sources:

(1) In-depth Interviews

In-depth interviews were conducted with ten key informants to gather comprehensive and contextual information related to the drug distribution supervision process. These informants consisted of pharmaceutical inspectors from BBPOM Serang, responsible pharmacists at distribution and service facilities, representatives from pharmacist and pharmaceutical technician professional associations, officials from the local health office, and regulatory experts. The interviews used a semi-structured format to allow flexibility in exploring the underlying causes of regulatory weaknesses, uncovering variations in supervisory practices, and understanding stakeholder perceptions of process gaps.

(2) Document Study

The study also involved a detailed analysis of official documents to support the data obtained through interviews. The documents reviewed included the Annual Reports and Performance Reports of BBPOM Serang from 2019 to 2024, macro and micro Standard Operating Procedures (SOPs) for pharmaceutical and food production and distribution, inspection result reports, and CAPA documentation submitted by facility supervisors or business owners. These documents provided historical and procedural context, allowing for triangulation of data and identification of patterns or inconsistencies between planned and actual practices.

(3) Limited Observation

Limited field observation was conducted during selected activities related to pharmaceutical supervision. These included attending supervision evaluation meetings, observing the CAPA verification process, and reviewing the workflows involved in digital data reporting. The goal of this observation was to directly understand how procedures are implemented in practice, evaluate the extent of alignment with written protocols, and identify potential process gaps, inefficiencies, or areas for improvement in the digital transformation efforts.

3.4 Data Analysis Technique

The analysis process was conducted through the following steps:

1) *Define*

The Define phase began with identifying key issues through the analysis of the Voice of Customer (VoC), which was obtained from in-depth interviews with relevant stakeholders. These VoC inputs were synthesized into a thematic map to categorize the core problems and critical quality needs as perceived by the users of the pharmaceutical supervision system. In addition, the Ishikawa diagram (also known as the fishbone diagram) was used to systematically classify the root causes into six dimensions: People, Methods, Materials, Machines, Environment, and Regulations. Combining VoC and the Ishikawa framework enabled a comprehensive mapping of issues from both empirical and systemic perspectives. This phase provided the foundation for determining the Critical to Quality (CTQ) elements that guided subsequent measurement and analysis phases.

2) *Measure*

In the Measure phase, the performance of supervisory processes was quantified using key time-based indicators, specifically Lead Time and Cycle Time, to evaluate the efficiency of follow-up actions after inspections. Moreover, process effectiveness was assessed through the calculation of Defects per Million Opportunities (DPMO), which represented the number of failed outcomes relative to total opportunities within supervisory follow-ups. In this study, the number of non-compliant facilities (Tidak Memenuhi Ketentuan/TMK) per facility type per year was counted and used to compute DPMO values. These values were then converted into Sigma Levels to assess statistical process capability. Altogether, these quantitative metrics provided a solid basis for identifying process variation and potential areas for improvement in the next phase.

3) Analyze

The Analyze phase involved identifying the root causes of problems in the drug distribution supervision process using the Failure Mode and Effect Analysis (FMEA) method. Each potential failure mode was evaluated using three parameters: Severity, Occurrence, and Detection, resulting in a Risk Priority Number (RPN). RPN scores were used to prioritize the most critical issues that demanded immediate corrective action. Additionally, Pareto analysis was employed to identify the most frequent types of violations that contributed to the majority of findings, in accordance with the Pareto Principle (80/20 Rule). These analytical tools helped the research to focus on high-impact problems, thus providing a data-driven foundation for designing targeted improvement strategies in the next phase.

4) Improve

During the Improve phase, data from the analysis stage were used to design problem-solving interventions that directly addressed the prioritized root causes. Thematic analysis of stakeholder recommendations was integrated with solution mapping based on Lean Six Sigma principles, such as waste elimination, process standardization, and digitalization. FMEA and Pareto outputs were used to prioritize improvement actions systematically. Furthermore, best practices in public regulatory policy and quality management were reviewed to ensure the proposed solutions were realistic and implementable. Each improvement proposal was evaluated based on resource availability, expected impact, and long-term sustainability. The output from this phase served as a basis for defining control indicators in the final phase.

5) Control

The Control phase focused on developing control indicators to ensure the sustainability of the implemented improvements. These included Service Level Agreements (SLAs) for CAPA follow-ups, pharmacist attendance monitoring, usage of digital systems, and the effectiveness of post-sanction coaching. Each control indicator was equipped with target metrics, monitoring methods, and periodic evaluation timelines. The feasibility of each control measure was reviewed using historical data and expert input. In addition, recurrence rates of violations were monitored as a long-term effectiveness indicator. The primary objective of this phase was to prevent recurrence of similar defects and maintain process performance within acceptable control limits, in line with Six Sigma principles.

3.5 Validity and Trustworthiness

To ensure the trustworthiness of the data, this study applied four core strategies in accordance with Lincoln and Guba's criteria [2]:

- Credibility

  Credibility was ensured through the use of member checking, a process in which the researchers returned quotes and preliminary data interpretations to the original informants for validation. This strategy helped to confirm the accuracy of the information gathered and ensured that the interpretations reflected the informants' actual experiences and perspectives.
- Transferability

  To achieve transferability, the study provided rich, contextual descriptions of BBPOM Serang's pharmaceutical supervision system. By offering detailed background information on institutional settings, supervisory structures, and regulatory challenges, readers are enabled to assess the applicability of the study's findings to other similar contexts.
- Dependability

  Dependability was addressed by conducting systematic coding and maintaining an audit trail. This included the use of qualitative data analysis software (such as NVivo) or manually constructed thematic tables to record coding decisions and analytic steps. The audit trail ensured that the research process could be traced and reviewed, contributing to methodological consistency and transparency.
- Confirmability

  To enhance confirmability, data triangulation was carried out across multiple sources, including interviews, documents, and observations. In addition, peer debriefing was conducted within the research team to discuss interpretations and mitigate potential researcher bias. This collaborative reflection supported objectivity and reduced the influence of personal assumptions on the analysis.

3.6 Research Ethics
This research has received approval from BBPOM in Serang and was conducted while maintaining the confidentiality of the interviewees' identities, institutional information, and internal documentation. Each participant was asked for written consent before the interview process was conducted.

4. RESULTS AND DISCUSSION
4.1 Characteristics of Interviewees and Descriptive Data
This study involved 10 key informants from regulators, pharmacists in charge/facility managers, health offices, and professional organizations. Selection criteria were based on direct involvement in the supervision process, depth of experience, and understanding of the quality system of drug distribution and pharmaceutical services. All informants provided ethical approval, and data were collected through in-depth interviews, observations, and internal supervision documents.

4.2 Findings and DMAIC Stages
4.2.1 Define
Identification of Key Issues through VoC, CTQ Tree, and Ishikawa Diagram
During the Define phase, four major issues were identified that hindered the effectiveness of drug distribution supervision conducted by BBPOM Serang. These issues were uncovered through the analysis of the Voice of Customer (VoC) derived from in-depth interviews with stakeholders, including regulators, pharmaceutical business actors, pharmacists, and institutional partners.

1. Ineffective CAPA Implementation

Most stakeholders revealed that the Corrective and Preventive Action (CAPA) documents submitted by pharmaceutical facilities were largely perfunctory, often using copied formats without incorporating root cause analysis (RCA). CAPA evaluations were mostly administrative, conducted without actual verification in the field. As a result, the same violations often recurred, indicating that the corrective actions failed to generate meaningful improvements. This problem highlights a critical gap in quality control, specifically the absence of a strong RCA system and standardized evaluation criteria for CAPA.

2. Weak Inter-Agency Coordination

Coordination among BBPOM and related institutions, such as local health offices, community health centers, and professional associations, was reported to be fragmented and non-operational. Stakeholders described issues such as overlapping inspection schedules, the absence of functional inter-agency evaluation forums, and inconsistencies in implementing follow-up actions. Furthermore, the lack of clarity between the functions of enforcement and guidance weakened the authority and impact of the risk-based supervision framework.

3. Non-Integrated Digital Supervision Systems

The supervision data was found to be distributed across multiple unlinked systems, including SIPT, SEHATI, and SMARTPOM. This fragmentation hindered the creation of a real-time integrated risk dashboard, leading to redundant reporting, delays in follow-up actions, and difficulty in determining baseline risks for each facility. In addition, some inspectors faced limited access and training in using digital tools, reducing the effectiveness of technology-based oversight.

4. Low Professionalism and Competency of Pharmaceutical Personnel

Many of the repeated violations were linked to the absence of pharmacists during inspections and their minimal involvement in implementing quality management systems. The understanding of CDOB regulations was often lacking, and training opportunities for pharmacy technicians were irregular. In some cases, pharmacists viewed their roles as merely administrative, leading to poor accountability. These findings suggest a systemic issue regarding the professionalism and capability of key personnel in pharmaceutical facilities.

Mapping of Critical to Quality (CTQ)
Following the VoC analysis, a Critical to Quality (CTQ) Tree was constructed to identify and break down the quality attributes expected by stakeholders into measurable indicators. Four main CTQ requirements were identified and further detailed.
1. Fast and SLA compliant follow-up response
2. Valid, verified and RCA-based CAPA evaluation
3. Clear and functional cross-agency coordination
4. Competent and professional pharmaceutical personnel

Each requirement is reduced to measurable CTQ Characteristics, such as timeliness of follow-up, completeness of RCA documents, frequency of active coordination forums, and pharmacist attendance ratio during inspections. The CTQ Tree helps to organize the focus of measurement in the next Measure stage.

Ishikawa Diagram Analysis (Cause-Effect Diagram)

To explore the causes behind the identified problems, the study utilized the Ishikawa Diagram. This tool allowed the classification of problem sources across six major dimensions:

1) Human (Man)

The unavailability of pharmacists during inspections and the lack of regular training for pharmacy technicians were noted as significant human-related contributors to non-compliance. Understanding and implementation of CDOB were inconsistent across facilities.

2) Method

CAPA practices were often superficial, involving template-based submissions that lacked meaningful root cause analysis. Evaluations were frequently reduced to checklist activities with no connection to process improvement.

3) System (Machine)

The lack of system integration created delays and made it difficult to generate a consolidated picture of risks. Existing platforms did not provide real-time risk dashboards, which are essential for proactive decision-making.

4) Data (Material)

Supervision data were stored in disparate formats and locations, preventing the establishment of baseline risk profiles and making data consolidation for follow-up actions challenging.

5) Environment

Inspectors reported high workloads and wide geographical areas to cover, many of which were difficult to reach. This affected inspection frequency and the ability to ensure timely and thorough supervision.

6) Regulation

The fragmentation of regulatory responsibilities and weak enforcement mechanisms, including a lack of harmonized disciplinary approaches, limited the deterrent effect of existing oversight structures.

The diagram clearly showed that the problems were systemic, with interlinked causes that required cross-functional collaboration and integrated interventions rather than isolated technical fixes.

The Define phase successfully outlined four central problems, which include ineffective CAPA, weak inter-agency coordination, fragmented digital systems, and low professionalism of pharmaceutical personnel. These issues were identified as key inhibitors of effective supervision. The problems were mapped through the analysis of the Voice of Customer, then translated into measurable quality needs using the Critical to Quality (CTQ) Tree, and further analyzed through the Ishikawa Diagram. The findings underscored that the underlying causes were systemic and multifactorial, requiring integrated and data-driven improvement strategies. This foundation provides a strong basis for the next phases of the research, particularly the Measure and Analyze phases, in which performance indicators and root cause prioritization will be examined in greater depth.

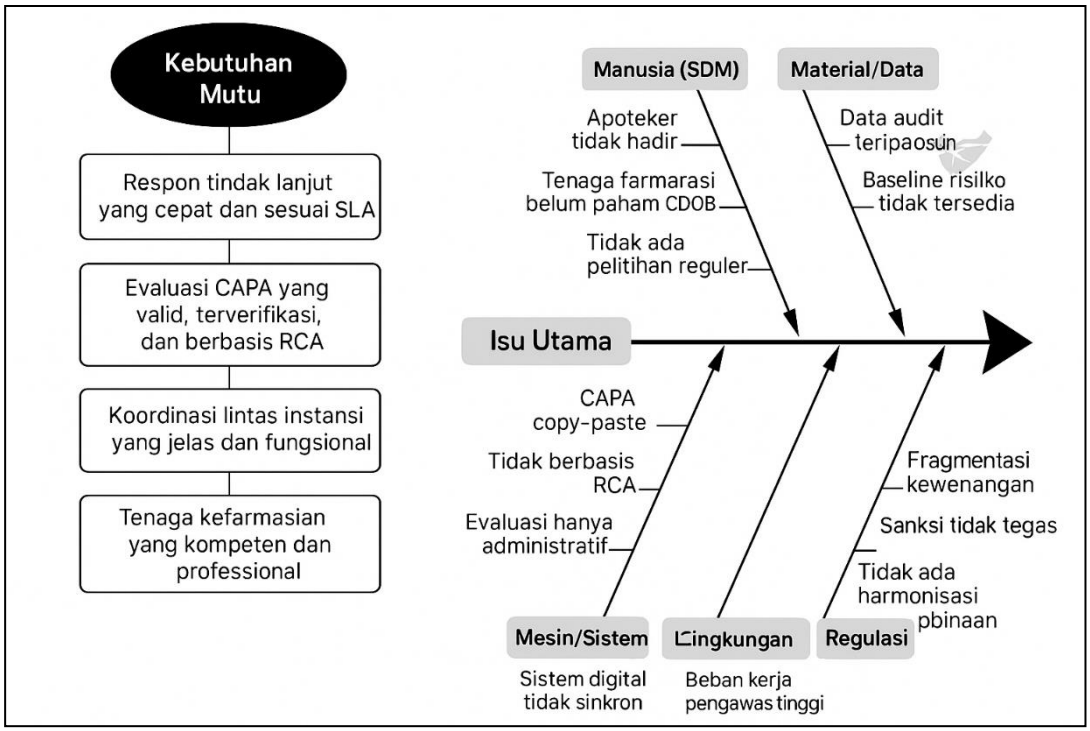

Fig 1. Mapping of Supervision Issues Based on CTQ and Ishikawa Diagram

4.2.2 Measure

The Measure phase in the Lean Six Sigma approach aims to map the actual performance of the process, quantify the degree of nonconformity (defect), and provide an objective foundation for prioritizing improvements. In this study, four main indicators were used to analyze the capability of the drug distribution supervision process: Defects per Million Opportunities (DPMO), Sigma Level, Lead Time, and Cycle Time.

***1. Defects per Million Opportunities* (DPMO) and *Sigma* Level**

DPMO is used to measure the number of errors or defects per one million inspection opportunities. The inspection data from 2019 to 2024 revealed a significant variation in DPMO values across different types of facilities. Drug stores recorded the highest DPMO value of 78,571 with a Sigma Level of 2.91. This indicates very low process capability and frequent regulatory violations. Pharmacies and clinics had DPMO values ranging between 39,214 and 42,161, with Sigma Levels from 3.23 to 3.30. These numbers suggest moderate but still unstable performance. On the other hand, community health centers (Puskesmas) and government pharmaceutical installations (IFP) had the lowest DPMO values at 3,691 and 9,836, with corresponding Sigma Levels of 4.18 and 3.83, indicating high and stable process capability.

These findings highlight that drug distribution facilities, particularly drug stores, pharmacies, and clinics, require serious attention due to their high defect rates. Such conditions may undermine the quality of supervision and pose risks to patient safety. High defect levels point to a need for targeted improvement efforts in these facilities.

The overall average DPMO across all facility types was 31,917, and the average Sigma Level was 3.48. These figures indicate that the current supervision process capability remains unstable and fluctuating. The fact that the Sigma Level has not yet reached 4.0 implies that the system is still below high-quality performance standards. Therefore, improvement interventions based on Lean Six Sigma are both relevant and urgent, especially for facilities with high DPMO values such as drug stores, clinics, and pharmacies.

2. Lead Time

Lead time was measured from the date of inspection until the entire Corrective and Preventive Action (CAPA) process was officially closed. The findings showed that the average lead time reached 105 working days, with extreme cases such as Klinik Sahabat Sehat requiring up to 121 working days, far exceeding the established Service Level Agreement (SLA) of 35 working days for inspectors and 21 working days for facilities. This

significant delay indicates the presence of process defects, including idle time, waiting, and rework, especially due to repetitive CAPA submissions that lack Root Cause Analysis (RCA). Excessively long lead times reduce the effectiveness of supervision and diminish the preventive impact against recurring violations.

3. Cycle Time

Cycle time was defined as the actual time required to complete one full inspection cycle, including opening the visit, conducting interviews, verifying documents, collecting evidence, delivering education, and signing the inspection report (BAP). The average cycle time across all facility types was 222 minutes (approximately 3.7 hours). The highest cycle times were recorded at Pharmaceutical Wholesalers (PBF) with 440 minutes (7.3 hours) and Government Pharmaceutical Installations (IFP) with 380 minutes (6.3 hours). In contrast, pharmacies, clinics, and drug stores had the lowest cycle times at 125 minutes (2.08 hours). The longer cycle times in PBFs and IFPs reflect the complexity of document verification and distribution mechanisms, while the shorter cycle times in smaller facilities suggest simpler processes. These variations also indicate the need for a risk-based inspection strategy, where high-risk facilities receive more intensive oversight and better allocation of human resources.

4. Combined Interpretation (Cycle Time vs. Lead Time vs. DPMO-Sigma)

There is a significant discrepancy between the average Lead Time (±105 working days) and Cycle Time (3.7 hours), revealing that value-added time constitutes less than 10% of the total process time. The remaining time represents waste, including delays in document disposition, repeated CAPA assessments, and manual administrative processes. This comparison clearly demonstrates that the majority of the supervision process consists of non-value-added activities. These inefficiencies must become a central focus in the subsequent Improve and Control phases.

In general, the Measure Stage is described as follows:

1. Process capability is still inadequate, indicated by an average Sigma Level of 3.43 and a high DPMO in Pharmacies and Drug Stores.
2. The long Lead Time shows the accumulation of waste due to the verification and disposition process that is not standardized and has not been digitized.
3. Varying Cycle Time reflects differences in workload and complexity between facilities, emphasizing the importance of segmenting inspection strategies.
4. All these quantitative indicators prove that BBPOM Serang's supervision process is not systemically optimal, and requires data and risk-based interventions in the next stage of improvement.

4.2.3 Analyze

The Analyze phase plays a critical role within the DMAIC cycle (Define, Measure, Analyze, Improve, Control), as it aims to identify and prioritize the root causes of inefficiencies in the quality supervision of drug distribution. In this study, two primary analytical tools were employed: Failure Mode and Effects Analysis (FMEA) and the Pareto Diagram.

FMEA was utilized to assess 53 specific issues (children nodes) that were grouped into eight major thematic categories (parent nodes). Each issue was evaluated using three key parameters:

- Severity (S): the extent of the impact caused by the failure,
- Occurrence (O): the frequency at which the failure is likely to occur,
- Detection (D): the difficulty of detecting the failure before it impacts the process.

The Risk Priority Number (RPN) was calculated by multiplying these three parameters (RPN = S × O × D). This value served as a quantitative basis for ranking and prioritizing the problems requiring immediate corrective actions. The table below presents the top ten issues with the highest RPN values identified in this analysis:

Table 1. Root Cause Prioritization Based on the Highest RPN Value (FMEA Analysis Results)

No	Main Theme	Root Cause	RPN
1	Ineffective CAPA	CAPA is not based on Root Cause Analysis (RCA)	378
2	Ineffective CAPA	CAPA is just an administrative formality	336

3	Audit & Follow-up	Sanctions fail to produce a deterrent effect	336
4	Pharmaceutical Human Resources	Pharmacy personnel lack understanding of distribution regulations	336
5	Pharmaceutical Human Resources	Pharmacists only “lend their name” without playing an active role	324
6	Ineffective CAPA	CAPA has no real impact on improvement	324
7	Pharmaceutical Human Resources	Pharmacists hold multiple roles simultaneously	324
8	Pharmaceutical Human Resources	Lack of independence from business owners	315
9	Digitization System	Data not utilized for policy analysis	294
10	Weak Agency Coordination	Crisis team not active during critical situations	252

These results indicate that the failure modes with the highest Risk Priority Numbers (RPN) are systemic in nature, frequently recurring, and challenging to detect. The most critical issue, "CAPA not based on Root Cause Analysis (RCA)" with an RPN of 378, reflects a common pattern in which corrective actions are executed in an administrative manner without addressing the underlying technical causes. This leads to ineffective interventions and the absence of sustainable process improvements.

Furthermore, issues related to pharmaceutical human resources, such as the lack of understanding of relevant regulations, the tendency to serve in purely administrative capacities, and conflicts of interest, are among the high-impact failures. These issues are particularly difficult to identify during inspections because they are rarely documented or explicitly reported by the facilities involved.

Pareto Analysis

As a complement to the Failure Mode and Effects Analysis (FMEA), a Pareto diagram was developed by mapping the cumulative RPN values of all identified problems. The results revealed that the top 20 issues accounted for approximately 78% of the total accumulated risk, aligning with the Pareto 80/20 principle.
The dominant problems were associated with the following themes:

- CAPA and Quality Evaluation
- Competence and Commitment of Pharmaceutical Human Resources
- Audit and Follow-up Mechanisms
- Digital Systems and Inter-Agency Coordination

The Pareto diagram served as a strategic tool to focus improvement efforts and resources on a limited number of critical issues (the vital few) that contribute the greatest risk impact to the overall system.
Integration and Strategic Implications

The integration of FMEA and Pareto analysis yields several strategic insights:

1. The absence of Root Cause Analysis (RCA) in the CAPA process is the root of corrective actions that fail to address problems at their core. This leads to recurring violations.
2. Low involvement of pharmacists emerges as a latent issue with a low detection score, yet it has a substantial impact on the quality of pharmaceutical services.
3. Ineffective sanctions and weak institutional coordination indicate the need for improved governance and leadership in the supervision process.
4. The lack of integration in digital supervision systems hampers data analysis and the ability to make risk-based decisions.

Based on these findings, the recommended interventions in the Improve phase include:

- Implementation of RCA standards in CAPA evaluation.
- Development of a digital risk dashboard for data-driven monitoring.
- Regular technical training and capacity building for pharmaceutical personnel.

- Reforming inter-agency coordination forums for supervisory collaboration.

This stage of risk analysis shows that the root causes of ineffective supervision stem from systemic, regulatory, and human resource components. The FMEA provides a numerical mapping of problem priorities, while the Pareto Chart filters the focus of action based on cumulative risk levels.
Together, these tools form a solid foundation for designing strategic improvement interventions, which will be elaborated further in the Improve phase.

4.2.4 Improve

The Improve phase focuses on designing preventive solutions aimed at directly addressing the systemic root causes identified in the Analyze phase. This study adopts the principles of Lean Six Sigma, particularly by applying the Poka Yoke (mistake-proofing) approach, which seeks to prevent errors before they occur rather than simply correcting failures afterward. Based on problem prioritization using FMEA and Pareto analysis, four key areas of improvement were identified: ineffective CAPA implementation, low competence and commitment of pharmacists and pharmaceutical technicians, lack of integrated digital supervision systems, and weak inter-agency coordination.

The primary solution developed in this phase is the reformulation of a digital CAPA system based on Root Cause Analysis (RCA), equipped with mandatory fields and dual-layer validation features. Each CAPA form includes a compulsory RCA section, and the system is designed to prevent submission unless this field is completed. This feature serves as a Poka Yoke mechanism to deter superficial or administrative-only responses. Additionally, a two-step verification logic by auditors and structural supervisors is added to ensure that each CAPA submitted is thoroughly analyzed and contributes to genuine process improvement.

Another innovation introduced is the “Timer for Remember” feature, an automated reminder system that alerts both facilities and supervisors about deadlines for CAPA submission and evaluation. This function not only aims to improve compliance with service level agreements (SLAs), but also acts as a mistake-prevention tool to reduce delays, which have been a major form of defect.

During this phase, the SEHATI platform (Selaraskan Hasil Audit dan Tindak Lanjut Inspeksi) was developed as a digital desk tool to facilitate electronic CAPA reporting, uploading, and verification. This system is part of the Poka Yoke-based solution to prevent administrative delays and errors, incorporating features such as automatic reminders, upload time validation, and mandatory input fields including RCA. With SEHATI integration, the supervisory process becomes more transparent, accountable, and properly documented. A limited pilot implementation of these solutions has already been conducted in selected facilities. The results indicate improvements in CAPA document quality, timeliness, and pharmacist engagement in post-inspection actions. However, full-scale implementation still requires inter-agency regulatory support, information system alignment, and ongoing human resource capacity development.

Meanwhile, strengthening the role of the Regional Coordination Team for Drug and Food Supervision is identified as a key non-digital improvement strategy. Previously, this team was activated mainly during crises or mass enforcement events. In this phase, it is reoriented to function as a routine operational unit by mapping roles, assessing support needs, and more importantly, executing follow-up actions recommended by BBPOM Serang. This approach makes local-level drug and food supervision more collaborative, adaptive, and impactful in improving the quality of pharmaceutical services.

Beyond digital solutions, human-centered interventions were also implemented through technical training on RCA-based CAPA preparation and revisions to internal SOPs related to supervision and inspections. The training focused on enhancing the capacity of supervisors and quality managers in healthcare facilities to develop CAPA documents grounded in cause-and-effect analysis, rather than normative responses. The revised SOPs also include substance validation mechanisms, not just administrative checks, for each proposed corrective action.

In conclusion, the Improve phase in this study not only produces technical improvement recommendations but also designs systems that structurally prevent recurring errors. The Poka Yoke principle is applied not only at the digital system level but also within SOP design, training mechanisms, and inter-agency coordination governance. These interventions collectively strengthen the foundation for a more responsive, data-driven, and quality-oriented drug distribution supervision system.

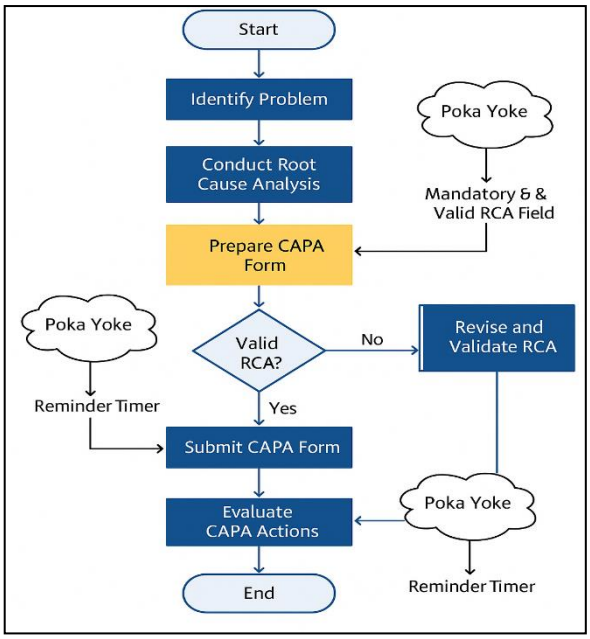

Fig 2. Flowchart of CAPA Process Based on Root Cause Analysis with Poka Yoke Integration in Pharmaceutical Surveillance

The flowchart illustrates the Corrective and Preventive Action (CAPA) process based on Root Cause Analysis (RCA), safeguarded by the Poka Yoke (mistake-proofing) principle. The process begins with problem identification, followed by RCA to determine the underlying causes. A CAPA form is then prepared, which must include a valid RCA. The system enforces compliance through mandatory RCA fields and an automated reminder system (Timer for Reminder). If the RCA is deemed invalid, the process is returned for revision. Once the form is complete and validated, the CAPA is submitted and evaluated. The application of Poka Yoke ensures both administrative and technical errors are prevented from the outset, promoting data-driven improvements and system accountability.

4.2.5 Control

The Control phase is the final step in the DMAIC (Define, Measure, Analyze, Improve, Control) cycle, aimed at ensuring the sustainability of the improvements developed during the Improve phase, preventing process backsliding, and strengthening the culture of quality in drug distribution supervision. In this study, control was implemented through three main approaches: updating Standard Operating Procedures (SOPs), digitalizing the supervision process, and applying a Control Plan based on both quantitative and qualitative indicators.

First, the micro-level SOP related to CAPA was revised to include mandatory Root Cause Analysis (RCA), dual validation by the pharmacist and facility leader, and a post-closure commitment field. These additions act as soft control mechanisms to ensure structural and moral involvement in quality assurance.

Second, the use of the SEHATI platform (Harmonize Audit Results and Follow-up Inspections) and the "Timer for Reminder" feature reinforces error-proofing and visual control principles of Lean Six Sigma. This digital system sends automated notifications to inspectors and business operators regarding deadlines for CAPA submissions and evaluations, and locks further processing if data is incomplete. SEHATI also enables real-time monitoring of Service Level Agreements (SLAs), integration of audit data, and a risk dashboard that supports data-driven decision-making.

Third, a comprehensive Control Plan was developed for 10 critical improvement areas, including control indicators, monitoring methods, responsible persons (PIC), and evaluation frequencies. Examples of control initiatives include:

- Evaluating CAPA effectiveness using indicators such as repeat findings and the proportion of CAPA documents with valid RCA;

- Monitoring CAPA SLA compliance through SEHATI's real-time dashboard;
- Strengthening inter-agency coordination through fixed coordination schedules and shared dashboards;
- Triannual or semiannual follow-ups by BBPOM, the District Health Office, and DPMPTSP on recommendations to freeze or revoke operational licenses.

Furthermore, this closed-loop control system aligns with the Lean Six Sigma 4.0 model proposed by Park et al. (2020), where control systems are not merely corrective but also preventive and adaptive to dynamic public sector risks.

The Control phase plays a vital role not only in sustaining improvement outcomes but also in building a resilient, integrated, and data-driven supervision system. In the context of pharmaceutical distribution and service oversight, digital tools like SEHATI and automated reminders have proven effective in fostering a more responsive and accountable process while reducing administrative errors. These tools enable faster, evidence-based decision-making and improve compliance with time and documentation standards. Additionally, involving organizational structures and cross-sectoral agencies in quality control signifies a shift from purely technical-operational oversight to governance-based surveillance. This transformation strengthens institutional accountability and enhances coordination between local and national supervisory authorities. Therefore, it can be concluded that the implementation of Lean Six Sigma, combined with organizational ownership and digital governance, is a highly relevant strategy for establishing an effective, sustainable, and adaptive drug supervision system in response to modern public health policy dynamics.

Overall, this research identifies four dominant issues in the drug distribution oversight carried out by BBPOM Serang: ineffective CAPA processes, weak inter-agency coordination, fragmented digital systems, and low professionalism among pharmaceutical personnel. These findings from the Define phase are supported by CTQ Tree mapping and Ishikawa Diagram analysis, indicating the systemic and multidimensional nature of the problems. This is reinforced by a key informant (AA), who stated, "CAPA is often just copy-pasted and does not address the real root of the problem," highlighting a fundamental weakness in the quality improvement mechanism. Other stakeholders, such as BB and DD, also emphasized the lack of coordination forums and the absence of a shared risk dashboard between BBPOM, the Health Office, and professional organizations, confirming the ineffectiveness of inter-institutional coordination.

In the Measure phase, process capability was assessed using DPMO, Sigma Level, Lead Time, and Cycle Time. Drugstores and pharmacies recorded the worst DPMO and Sigma Levels, indicating repeated non-compliance and weak inspection quality. Long Lead Times and varying Cycle Times across facility types reflect inefficiencies in supervision execution and resource allocation. As informant FF noted, "Follow-ups often take months just waiting for CAPA document evaluations," reflecting a bottleneck in the follow-up process.

The Analyze phase identified root causes using FMEA and Pareto analysis. The highest RPNs were found in CAPAs lacking RCA and low pharmacist involvement. The Pareto principle showed that 20 of the 53 problems contributed to the majority of the risks, justifying focused intervention on systemically impactful issues. As informant II highlighted, "Many pharmacists are absent during inspections or just submit their names," indicating low commitment and professionalism that directly affect the quality of on-site supervision.

In the Improve phase, solutions were designed using the Poka Yoke principle to prevent administrative errors from the outset. These included digital CAPA forms with automatic validation and a time-based reminder system. The SEHATI system enabled electronic and real-time CAPA monitoring. Non-digital interventions involved RCA training, SOP revisions, and strengthening the Regional Drug and Food Control Coordination Team. Initial successes were supported by informant GG, who stated, "With SEHATI and the reminder system, we know when and who needs to follow up, so there's no excuse for forgetting."

The Control phase focused on ensuring the sustainability of improvements. Controls included SLA monitoring, periodic CAPA evaluations, and risk dashboard utilization. Revised SOPs and digital systems enabled quicker, more accountable, and integrated decision-making. Thus, the Lean Six Sigma approach applied in this study fostered a data-driven, digitally governed continuous improvement cycle.

In conclusion, the implementation of Lean Six Sigma, supported by digital integration and inter-agency coordination, effectively addresses key challenges in drug distribution oversight. By employing tools such as FMEA, CTQ Tree, and Pareto Chart, this study successfully identified root causes and formulated RCA-based, error-proofed solutions. The SEHATI platform and reminder system demonstrably enhanced CAPA accuracy and SLA compliance. Collectively, these outcomes illustrate that the strategy not only improves process efficiency but also strengthens transparency and accountability in supervision. The developed model offers a strategic pathway toward a modern and sustainable pharmaceutical oversight system.

5. CONCLUSIONS AND SUGGESTIONS

5.1 Conclusion

This study demonstrates that the Lean Six Sigma (LSS) approach, through the DMAIC framework, can be effectively applied to identify root causes of inefficiencies in the drug distribution supervision system conducted by BBPOM in Serang. Several key findings can be concluded as follows:

1. The root causes of recurring findings in drug distribution oversight include ineffective CAPA implementation, weak inter-agency coordination, limited human resource capacity, and the lack of integration in digital monitoring systems.
2. The application of LSS helped to uncover process waste and defects, particularly in follow-up lead time, administrative-oriented CAPA processes, and the absence of Root Cause Analysis (RCA). Tools such as the Pareto Chart, Risk Priority Number (RPN), and CTQ Tree proved effective in systematically mapping improvement priorities.
3. Recommended improvements include standardizing RCA-based CAPA formats, digitalizing audit processes and follow-up SLAs, strengthening functional coordination forums, and developing an integrated and responsive supervision dashboard.
4. Improvement control mechanisms were designed using key success indicators such as SLA compliance within 35 working days, use of digital dashboards, and a significant reduction in repeated findings. These outcomes indicate that LSS can serve as a data-driven, process-oriented framework for reforming pharmaceutical oversight.

In conclusion, this study contributes to the development of a drug supervision model that is more collaborative, efficient, and adaptive to regulatory and technological changes.

5.2 Suggestion

Based on the findings and conclusions outlined above, the following recommendations are proposed:

- For BBPOM and national regulators: It is essential to integrate Lean Six Sigma (LSS) principles into national pharmaceutical supervision policies, including regular training on Root Cause Analysis (RCA) and the implementation of risk-based auditing systems. Reporting platforms such as SIPT and SEHATI should be harmonized into a single national analytics platform.
- For regional cross-sector agencies: There is a need to revitalize cross-sector coordination teams at the provincial, municipal, and district levels to function not only administratively but also operationally and based on real-time data.
- For pharmaceutical business operators: Intensive capacity building is needed regarding quality management, high-quality CAPA reporting, and the ethical responsibilities and professionalism of pharmacists.
- For future research: Quantitative studies are recommended to measure the effectiveness of LSS implementation, as well as to explore the role of artificial intelligence in supporting predictive risk-based pharmaceutical surveillance.

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