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Analysis of Pharmacists Duties and Functions in The Implementation of Good Cosmetics Manufacturing Practices in The Cosmetics Industry: A 4m + 1e Fishbone Analysis

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ABSTRACT

Backgorund: The implementation of *Good Manufacturing Practices* (GMP), or Good Cosmetic Manufacturing Practices (CPKB), is essential to ensure the quality, safety, and consistency of cosmetic products. Pharmacists play a crucial role in quality assurance, validation, documentation, and production process control. **Objective:** This study aimed to evaluate the contribution of pharmacists' roles and responsibilities to the implementation of GMP/CPKB and to identify the causes of nonconformities using a fishbone diagram based on the 4M + 1E approach. **Method:** A descriptive mixed-methods design was employed through in-depth interviews and a Likert-scale questionnaire (1–5) administered to three responsible pharmacists from PT ABC, PT DEF, and PT XYZ. The research instrument consisted of 10 assessment items covering the aspects of man, method, material, machine, and environment. The level of GMP/CPKB implementation was calculated by comparing the actual score with the maximum possible score and expressing the result as a percentage. **Results:** The results showed that the average GMP/CPKB implementation scores were 4.96 (99.2%) for PT ABC, 4.92 (98.4%) for PT DEF, and 4.88 (97.6%) for PT XYZ, out of a maximum score of 5. All companies were classified in the good category (81-100%). However, several nonconformities were still identified in the areas of human resources, work methods, raw materials, equipment, and the production environment. Fishbone analysis revealed that the main contributing factors included inconsistent personnel discipline, delays in updating Standard Operating Procedures (SOPs), variations in raw material quality, limitations in equipment facilities, and suboptimal environmental control. **Conclusion:** This study highlights the importance of pharmacists' contributions in supporting GMP/CPKB implementation through quality system supervision and control. Nevertheless, the findings remain descriptive in nature due to the limited number of respondents, consisting of only three participants.

Keywords: pharmacist, diagramfishbone, GMP, duties and functions, cosmetics industry

INTRODUCTION

The cosmetics industry in Indonesia is projected to grow by 5.35% annually between 2024 and 2028. This growth has led to an increasing need for professionals, including pharmacists, especially in the areas of formulation, production, quality control, and risk management (Purnomo et al., 2025). Good Manufacturing Practices (GMP) ensuring the quality, safety, and consistency of cosmetic products throughout the production process (Syahid and Jumiono, 2025). The cosmetics industry implements GMP to prevent contamination, maintain product stability and effectiveness, and protect consumers from health risks resulting from products that do not meet requirements (Anastasya et al., 2025). Regulations related to GMP have been established by BPOM, ASEAN Cosmetic Directive (ACD), andEuropean Medicines Agency (EMA). Compliance with GMP in Indonesia is a basic requirement for issuing distribution permits and quality certification for the cosmetics industry.

The implementation of GMP at the industrial level still faces challenges despite the availability of comprehensive technical guidelines. Companies often experience limited professional

staff, non-compliance with standard operating procedures, and weak internal quality control. Pharmacists are strategically positioned to address these challenges through core duties and functions encompassing formulation, production, documentation, quality control, and workforce training. Variations in the level of pharmacist involvement in each role have the potential to impact the consistency of GMP implementation (Wirasuta et al., 2025).

Analysis of the causes of GMP non-conformance requires a systematic approach. Diagramfishbone provides a root cause mapping tool based on human categories (Man), material (Material), equipment (Machine), working method (Method), and environment (Environment) (4M + 1E) (Hendro et al., 2023). This technique helps the industry identify sources of non-conformities in a structured manner and formulate appropriate corrective actions. Many studies have been conducted on GMP implementation in the cosmetics industry, but research that specifically assesses the contribution of pharmacists' duties and functions using analysis fishbone is still very limited. The absence of such studies creates a knowledge gap regarding the extent to which pharmacists' role influences the successful implementation of GMP.

This study aims to analyze the contribution of pharmacists' duties and functions to the implementation of GMP using a diagram approach fishbone. This study also identifies the root causes of GMP non-compliance and assesses the relationship between pharmacist involvement and potential deviations. The results are expected to provide benefits in the form of strengthening scientific evidence regarding the role of pharmacists in the cosmetics industry, supporting the industry in improving quality management, and providing input to regulators in developing policies related to pharmacist competency. The findings of this study are expected to contribute to improving the quality, safety, and competitiveness of national cosmetic products.

MATERIALS AND METHODS

Research Design and Setting

This study employed a descriptive case study design with a mixed-methods approach (qualitative and quantitative) to explore the roles and responsibilities (main duties and functions) of pharmacists in the implementation of Good Manufacturing Practices for Cosmetics (GMP/CPKB) in the cosmetic industry. Data were collected through the integration of questionnaires and in-depth interviews. This study was exploratory in nature and was not intended to provide population-level generalizations. The research was conducted over a period of two months in three national cosmetic industries, namely PT ABC, PT DEF, and PT XYZ. These companies were selected purposively based on the following criteria: having active GMP/CPKB certification, producing skincare and body care products, and employing pharmacists in the Production, Quality Assurance (QA), or Quality Control (QC) units.

Research Respondents

The respondents consisted of three pharmacists responsible for GMP/CPKB implementation from each company. The inclusion criteria were pharmacists who were directly involved in GMP/CPKB implementation, held at least a supervisor-level position or served as the person in charge of Production, QA, or QC units, had a minimum of two years of work experience, and were willing to participate in interviews and complete the questionnaire.

Type and Source of Data

The data collected in this study were primary data obtained through in-depth interviews and questionnaires. Interviews were conducted to explore the implementation of pharmacists' duties and responsibilities, barriers to GMP/CPKB implementation, and factors contributing to non-conformities. Meanwhile, questionnaires were used to assess the level of pharmacist involvement based on the fishbone 4M + 1E approach.

Research Instruments

The research instruments consisted of a semi-structured interview guide and a closed-ended questionnaire using a 5-point Likert scale. The questionnaire was developed based on the fishbone 4M + 1E approach (Man, Material, Machine, Method, and Environment). Each category consisted of 10 items reflecting aspects of GMP/CPKB implementation, including raw material procurement, production control, quality assurance, documentation, human resource training, environmental

hygiene, and pharmacovigilance. The instrument was used to measure the level of pharmacist involvement in GMP/CPKB implementation.

Validity and Reliability Testing of the Instrument

Content validity testing was performed using the Item Content Validity Index (I-CVI) and Scale Content Validity Index (S-CVI), assessed by three expert validators consisting of one academic expert in industrial pharmacy and two senior pharmacists from the cosmetic industry. Items were considered valid if the I-CVI value was ≥0.78, while the instrument was considered acceptable if the S-CVI value was ≥0.90. The validation results showed that the I-CVI values ranged from 0.80 to 1.00, with an S-CVI value of 0.95. Reliability testing using Cronbach's alpha demonstrated a value greater than 0.70, indicating that the instrument was reliable.

Data Collection and Data Analysis

Data collection was conducted through semi-structured interviews lasting approximately 30–60 minutes, either conducted face-to-face or online, followed by questionnaire completion. To minimize social desirability bias, the identities of respondents and companies were anonymized. Quantitative data were analyzed descriptively using the percentage of Likert scale scores, categorized as good (81-100%), moderate (51–80%), and poor (<50%). Qualitative data were analyzed using thematic coding through the stages of open coding, categorization, and identification of major themes. The findings were subsequently mapped using a fishbone 4M + 1E diagram to identify the root causes of problems. Method triangulation was performed by comparing interview findings, questionnaire results, and supporting documents, including Standard Operating Procedures (SOPs), batch records, and organizational structures.

Research Ethics

This study obtained written permission from each participating cosmetic industry. All respondents provided informed consent prior to participation. Data confidentiality was maintained by anonymizing the identities of companies and individuals and restricting the use of data solely for research purposes.

RESULTS

GMP/CPKB Implementation Level

The results of the study showed that the implementation of Good Manufacturing Practices (GMP/CPKB) in PT ABC, PT DEF, and PT XYZ was categorized as good, with high compliance scores based on questionnaire evaluation. The average scores were: PT ABC: 4.96 (99.2%), PT DEF: 4.92 (98.4%), PT XYZ: 4.88 (97.6%). All companies were classified in the "good" category (81-100%), indicating that GMP/CPKB implementation across the 4M + 1E aspects was well established.

Table 1. Summary of GMP/CPKB Implementation Scores Based on the 4M + 1E Aspects

Aspect	PT ABC	PT DEF	PT XYZ
Man (Human Resources)	4.7 (94%)	4.5 (90%)	4.7 (94%)
Method (Work Procedures)	4.9 (98%)	4.8 (96%)	4.8 (96%)
Material (Raw Materials and Packaging Materials)	4.9 (98%)	4.9 (98%)	4.9 (98%)
Machine (Equipment)	4.8 (96%)	4.7 (94%)	4.8 (96%)
Environment (Work Environment)	5.0 (100%)	4.7 (94%)	4.9 (98%)
Overall Average Score	4.96 (99.2%)	4.92 (98.4%)	4.88 (97.6%)

4M + 1E Fishbone Analysis Results

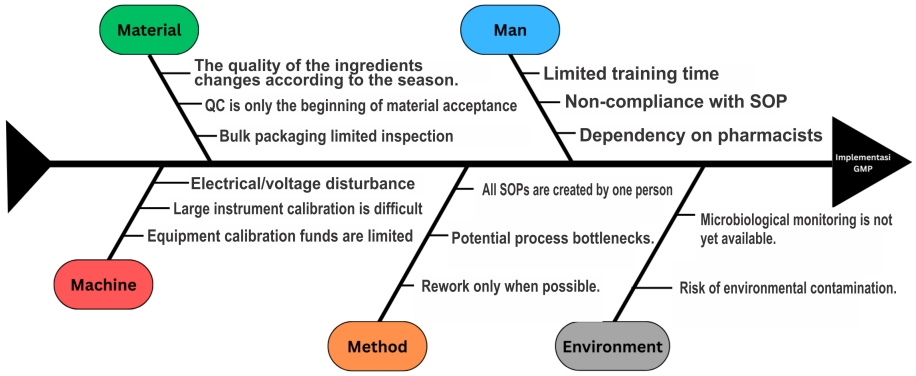

Figure 1.Diagram Analysis Fishbone PT ABC

Table 2.Problems and Solutions to the Problems of Implementing GMP 4M + 1E at PT ABC

Aspect	Problems Found	Repair Solution
Man (HR)	1. Limited training time 2. Non-compliance with SOP 3. Dependence on pharmacists	1. Applymicro-trainingperiodic (short, specific,shift-based) And e-learning for compulsory material 2. Routine internal audits and implementation of rewards and punishments based on documentation compliance 3. Cross-training for knowledge transfer and delegation of tasks in accordance with regulations
Method (Working method)	1. All SOPs are created by one person 2. Potential bottleneck process 3. Rework only if possible	1. Form a team drafting Cross-departmental SOP and QA as reviewer 2. Process flow analysis (VSM) and critical step improvement to speed up workflow 3. Implement critical controls early in the process to prevent products from progressing to expensive stages.
Material (Raw Materials and Packaging)	1. The quality of the ingredients changes according to the season.	1. Batch standardization with active marker testing and specification adjustment 2. Periodic re-test during

Aspect	Problems Found	Repair Solution
	2. QC is only the beginning of material acceptance 3. Limited inspection bulk packaging	storage according to the retest date and FEFO 3. Representative sampling and additional inspections (visual and integrity check)
Machine (Equipment)	1. Electrical/voltage disturbance 2. Calibration of large instruments is difficult 3. Limited tool calibration funds	1. Install UPS andstabilizeron critical machines 2. Schedule calibrationin-housewith vendorsmobile service 3. Critical equipment calibration priorities based on quality and safety risks
Environment (Work environment)	1. Microbiological monitoring does not exist yet 2. Risk of environmental contamination	1. ApplyEnvironmental Monitoring Program (settle plate/air sampling) 2. Risk-based scheduled production and sanitation area zoning

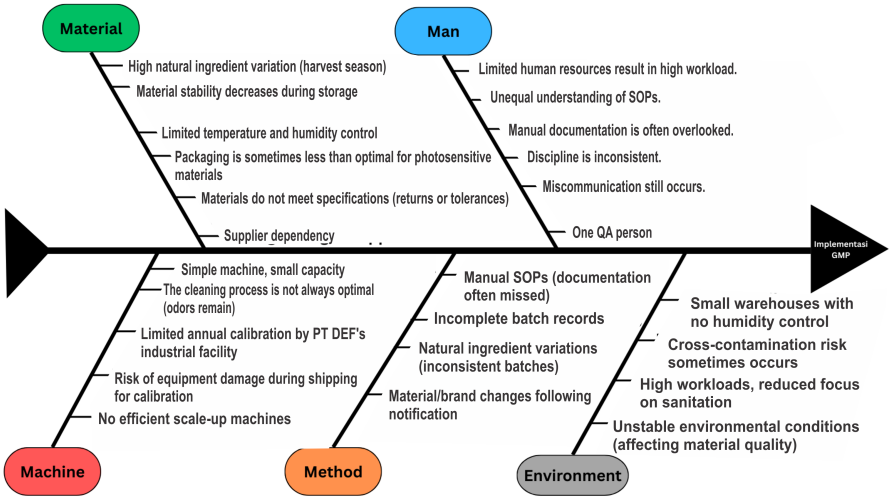

Figure 2. Diagram AnalysisFishbone PT DEF

Table 3. Problems and Solutions to Problems in the Implementation of GMP 4M + 1E at PT DEF

Aspect	Problems Found	Repair Solution
Man (HR)	1. Limited human resources 2. understanding of SOPs is uneven 3. Inconsistent discipline 4. Communication	1. Phased recruitment or redistribution of tasks based on competency and production priorities 2. Program refresh training periodically with competency evaluation

Aspect	Problems Found	Repair Solution
	sometimes miscommunication 5. QA only 1 person 6. Manual and often overlooked documentation	3. System implementation checklist daily plus reward And punishment 4. Briefing daily between divisions andlog-bookstructured communication 5. Add QA personnel orcross-training QC to support QA 6. Document digitalization (e-BR,e-logbook) gradually
Method (Working method)	1. SOP Manual (documentation often overlooked) 2. Batch record is incomplete. 3. Natural ingredient variation (batch not suitable) 4. Changes in materials/brands subject to notification	1. Implementation of digital documentation system (e-SOP ande-logbook) with notification andchecklist mandatory before the process continues (prevent human error). 2. Apply in-process checklist per process stage with QA verification before the process can continue (hold step). 3. Standardize raw materials through active compound marker tests and formula adjustments based on the results of the analysis of the levels of each batch. 4. Create a Procedure Change Control which requires quality evaluation and comparative testing before new suppliers or materials are approved.
Material (Raw Materials and Packaging)	1. Variations of natural materials 2. The stability of raw materials decreases during storage. 3. Temperature and humidity control is not optimal 4. Packaging does not meet the needs of photosensitive products 5. Material does not	1. Standardization of materials with quality testing and marker-based formulation adjustments 2. Controlled storage (temperature/humidity control) and FIFO/FEFO 3. Add automatic monitoring sensors with alarms 4. Use amber/foil packaging with anti-UV coating 5. Quality contracts with suppliers and supplier audits

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Aspect	Problems Found	Repair Solution
	meet specifications (return) 6. Supplier dependency	6. Diversification of suppliers and stock buffer critical materials
Machine(Equipment)	1. Simple machine, small capacity 2. Tool cleaning is not always optimal 3. Limited annual calibration of facilities 4. Risk of damage to the equipment during calibration delivery 5. There are no efficient scale-up machines	1. Upgrade machines in stages according to production projections 2. Detailed cleaning SOP with verificationcleaning 3. Contract with the nearest service vendor and backup schedule 4. Calibration in-house portable If possible 5. Medium scale machine investment study and testing trial scale
Environment (Work environment)	1. Small warehouse without humidity control 2. Risk of cross-contamination of product aromas 3. High workload reduces sanitation focus 4. Unstable environment affects the quality of materials	1. Install dehumidifier and air circulation settings 2. Scent-based production area separation +airflow control 3. Structured sanitation schedule & dedicated staff allocation 4. Periodic environmental monitoring andcorrective action fast

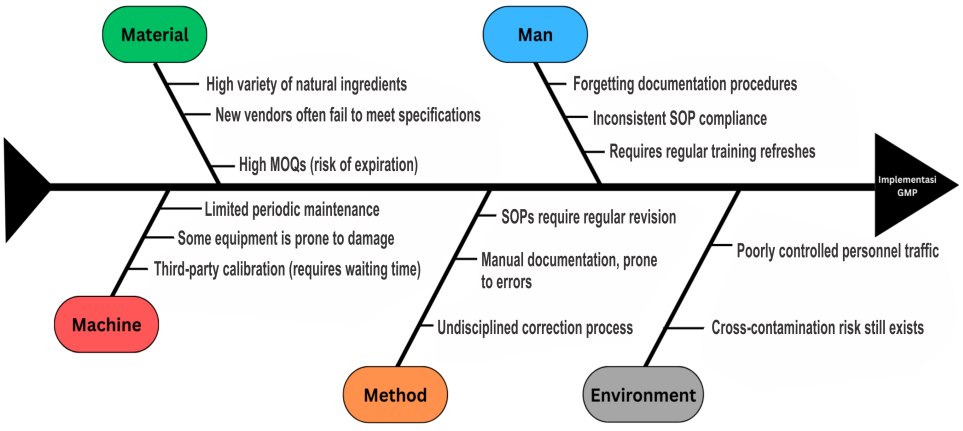

Figure 3. Diagram Analysis Fishbone PT XYZ

Table 4. Problems and Solutions to Problems in the Implementation of GMP 4M + 1E at PT XYZ

Aspect	Problems Found	Repair Solution
Man (HR)	1. Forgot documentation procedures 2. SOP compliance is inconsistent 3. Need refresh regular training	1. Use checklist mandatory in each process, as well as visual reminders in the work area 2. Periodic compliance audits and feedback immediately to the operator (corrective coaching) 3. Periodic training program based ongap competency and deviation records
Method (Working method)	1. SOPs need periodic revision 2. Manual documentation, prone to errorserror 3. The correction process is not yet disciplined	1. Set review SOP once a year and change control for immediate updates 2. Gradual transition to digital systems (e-BR/e-log) for critical areas 3. Implement QA verification on every correction and training Good Documentation Practice
Material (Raw Materials and Packaging)	1. High variety of natural materials 2. New vendors often do not meet specifications 3. Large MOQ (risk of expiration)	1. Standardization of raw materials based on active markers and fixed quality parameters 2. Vendor qualification including initial audit and performance rating periodically 3. Flexible MOQ negotiations and demand-based purchasing planning forecast production
Machine(Equipment)	1. Limited periodic maintenance 2. Some tools are prone to damage 3. Third party calibration (requires waiting time)	1. Create Preventive Maintenance Plan scheduled (mandatory engine logbook) 2. Analysis root causeand perform early replacement of critical components 3. Schedule calibration offset and use the tools backup during the calibration period
Environment (Work	1. Personnel traffic is poorly controlled	1. Area zoning and clear entry/exit routes and limited

Aspect	Problems Found	Repair Solution
environment)	2. The risk of cross-contamination can still occur	access 2. Strict sanitation procedures and separation of areas based on product characteristics

Empirical Findings from Interviews

The interview results showed several operational realities: PT ABC: need for improved training and SOP compliance, PT DEF: high turnover and manual documentation issues, PT XYZ: need for refresher training and documentation errors. These findings indicate inconsistencies between SOP implementation and field practice despite high compliance scores.

Table 5. Empirical Findings Based on Interviews and Questionnaires

Aspect	Evidence of Empirical Findings	Impact on GMP
Man (Human Resources)	Respondents from PT ABC stated that improvements in internal training and discipline in the use of Personal Protective Equipment (PPE) among some production personnel are needed.	Risk of inconsistency in the implementation of personal hygiene practices and SOPs.
	Respondents from PT DEF stated that there is a relatively high personnel turnover rate, resulting in uneven understanding of CPKB among employees.	Risk of inconsistency in SOP implementation.
	Respondents from PT XYZ stated that periodic refresher training is needed because some personnel are still found to forget documentation procedures.	Risk of human error and documentation non-conformities.
Method (Work Procedures)	Respondents from PT ABC stated that SOP preparation and revision are still centralized in one personnel, causing delays in document updates.	Risk of inconsistency between documentation and operational practices.
	Respondents from PT DEF stated that documentation is still performed manually and managed by a limited number of personnel.	Risk of delayed SOP revisions and human error.
	Respondents from PT XYZ stated that periodic SOP revisions still require acceleration to align with the latest operational conditions.	Risk of non-compliance in procedure implementation.
Material (Raw Materials and Packaging Materials)	Respondents from PT ABC stated that seasonal variations in raw material quality are still found in several natural ingredients.	Risk of product quality instability between batches.
	Respondents from PT DEF stated that variations in natural materials and supplier changes contribute to differences in raw material quality.	Risk of product quality instability.
	Respondents from PT XYZ stated that inconsistencies in quality from new vendors are still found for several raw materials.	Risk of variations in final product quality.

Machine (Equipment)	Respondents from PT ABC stated that several pieces of equipment still require periodic evaluation to ensure ease of cleaning and sanitation processes.	Risk of cross-contamination if sanitation procedures are not optimal.
	Respondents from PT DEF stated that machine capacity remains limited and there is a risk of equipment damage during external calibration processes.	Potential disruption of the production process.
	Respondents from PT XYZ stated that equipment maintenance and calibration require more consistent monitoring.	Risk of decreased production process effectiveness.
Environment (Work Environment)	Respondents from PT ABC stated that environmental microbiological monitoring has not yet been conducted routinely.	Risk of contamination in the production environment.
	Respondents from PT DEF stated that warehouse humidity control and production area management are not yet optimal.	Risk of material quality deterioration and environmental contamination.
	Respondents from PT XYZ stated that personnel movement control within production areas still needs to be strengthened.	Risk of cross-contamination in clean areas.

Aspect-Based GMP Scores

The results per aspect were: Man: 90%-94%, Method: 96%-98%, Material: 98%, Machine: 94%-96%, Environment: 94%-100%. The lowest performance was found in the Man aspect, while Material and Environment showed the highest scores.

DISCUSSION

4M + 1E Fishbone Analysis Results

Analysis of GMP implementation (Good Manufacturing Practices) in the cosmetics industry PT ABC, PT DEF, and PT XYZ using diagrams fishbone through the 4M + 1E approach which consists of several aspects, including the human aspect (Man), material (Material), equipment (Machine), working method (Method), and environment (Environment) (4M + 1E). The approach aims to identify the root of the problem in each cosmetic industry in a structured manner to develop recommendations for improvement. Data were obtained through interviews and questionnaires which were then further analyzed to assess the extent to which GMP principles have been implemented effectively in each aspect. Before the questionnaire was distributed, the questionnaire instrument used in this study was first validated through a content validity test to ensure its suitability for use. Content validity (content validity) was assessed by three experts, consisting of one lecturer with expertise in pharmacy and two senior pharmacists with more than five years of experience in GMP implementation in the cosmetics industry. The experts assessed each questionnaire item based on clarity, relevance to the research variables, and appropriateness of terminology to the GMP context using a four-point scale. Validity scores were then calculated using Item Content Validity Index (I-CVI) and Scale Content Validity Index (S-CVI), where an item is declared valid if it has an I-CVI $\geq$ 0.78 and an S-CVI $\geq$ 0.90 (Fahrurrozi et al., 2025). The assessment results showed that all questionnaire items obtained an I-CVI value between 0.80-1.00 with an S-CVI value of 0.95, so the instrument was declared to have very good content validity.

Analysis 4M + 1E

According to Syahid and Jumiono (2025), GMP evaluation can be performed using an Ishikawa/fishbone diagram because it systematically maps the root causes of problems based on the 4M + 1E approach, thereby facilitating the identification of non-conformities and the development of

appropriate corrective actions. Wibowo et al. (2025) also stated that the fishbone diagram is an effective tool for visually and comprehensively illustrating the sources of production problems and demonstrating the relationships among contributing factors to support targeted corrective actions. The findings of this study indicate a gap between high levels of administrative compliance and the challenges encountered in daily operational implementation. This condition may be influenced by the use of self-report instruments completed by responsible pharmacists, which tend to reflect a positive perception of compliance. Therefore, the results should be interpreted cautiously and should not be considered equivalent to external audits or objective observations.

The interview findings and fishbone analysis continued to reveal operational challenges despite the high compliance scores, emphasizing that GMP/CPKB implementation does not solely depend on written SOPs but also requires consistency in execution, continuous supervision, and ongoing evaluation. The results of the 4M + 1E analysis are subsequently presented along with the fishbone diagram.

Based on the questionnaire results from PT ABC, PT DEF, and PT XYZ, the average GMP/CPKB implementation scores obtained were 4.96, 4.92, and 4.88 out of a maximum score of 5, equivalent to 99.2%, 98.4%, and 97.6%, respectively. The percentage was calculated by comparing the total score with the maximum possible score and was classified into good (81-100%), moderate (51-80%), and poor (<50%) categories (Widjanarko and Anggoro, 2021). All companies were categorized as "good," reflecting a strong and consistent quality management system implementation across the 4M + 1E aspects, with pharmacists playing an active role in controlling human resources, materials, facilities, documentation, and the production environment. However, several challenges were still identified, particularly in the human resource aspect, including personal hygiene practices, the use of personal protective equipment (PPE), and the competency of newly recruited personnel. In addition, non-technical issues were also observed, such as high employee turnover, delays in SOP updates, and production target pressures, which may affect the consistency of GMP/CPKB implementation. A summary of the 4M + 1E analysis is presented in Table 1.

The evaluation analysis of GMP/CPKB implementation in the three industries showed that although the compliance level was categorized as very good, potential operational non-conformities were still identified in several aspects. The Man (Human Resources) aspect had lower scores compared with other aspects across all companies. This finding was consistent with the interview results, which revealed challenges related to compliance with personal protective equipment (PPE) usage, delays in documentation, personnel turnover, and the need for periodic refresher training. Competency development and internal training programs have not fully covered all operational requirements, resulting in variations in SOP implementation consistency among individuals. In PT DEF, the Human Resources and Environment aspects obtained the lowest scores due to limited QA personnel, manual documentation systems, limited warehouse facilities, and inadequate humidity control. These findings are consistent with Paramita et al. (2025), who reported that human resource factors are among the main causes of GMP non-conformities, particularly related to personal hygiene compliance and consistency in SOP implementation.

The Method aspect obtained high scores across all companies because SOPs, batch records, and quality procedures were available and routinely implemented. However, the interview findings revealed that delays in SOP revisions and the risk of human error due to manual documentation systems still occurred, including in the processes of document verification, distribution, and updating, which were not yet fully optimized. This finding indicates that administrative compliance has been well established; however, the effectiveness of procedure implementation still requires further improvement. Syahid and Jumiono (2025) also stated that manual documentation systems and delays in SOP updates may increase the risk of human error; therefore, digitalization of the system is needed to improve the accuracy and efficiency of quality control and monitoring.

In the Material aspect, high scores were obtained due to the implementation of raw material quarantine systems, Certificate of Analysis (CoA) verification, and supplier monitoring. However, several challenges remain, including variations in natural materials, supplier changes, and the potential decrease in material stability during storage, particularly at PT DEF and PT XYZ. Quality control during the stages of material receipt, storage, and repackaging still needs to be strengthened to

maintain product quality consistency. Therefore, although the material control system has been well implemented, material variability remains a potential factor that may affect the effectiveness of GMP/CPKB implementation.

The Machine and Environment aspects generally demonstrated good compliance with BPOM CPKB standards, particularly in facility sanitation, equipment calibration, and production area control. However, the interview results revealed several limitations, including machine capacity constraints, the risk of damage during external calibration processes, and suboptimal personnel traffic control. In addition, respondents highlighted the need to improve humidity control, environmental microbiological monitoring, and the strengthening of clean area zoning to prevent cross-contamination. BPOM RI (2019) emphasizes that sanitation and cross-contamination prevention are key components of CPKB; therefore, environmental monitoring must be carried out consistently even when compliance scores are high. This study also provides interview and questionnaire evidence to support the analysis and distinguish between empirical findings and the authors' interpretations, which are used to explain the root causes of issues related to the 4M + 1E aspects and their impact on GMP/CPKB implementation. A summary of the findings is presented in Table 5.

Although all companies achieved very high average scores (97.6%–99.2%), the interview results and fishbone analysis still revealed several operational issues, confirming that GMP/CPKB compliance is dynamic and depends on the consistency of implementation in practice. The high scores indicate that quality systems and GMP procedures are well established and implemented; however, the existence of such systems does not always guarantee that all processes operate optimally at all times. The discrepancy between the high compliance scores and the identified issues can be explained by the use of self-report instruments, which rely on respondents' perceptions, the presence of sporadic operational problems such as documentation delays and non-compliance with personal hygiene practices, as well as the fact that companies with well-established systems may still face consistency challenges due to production pressures, human resource turnover, and facility limitations.

The findings of this study indicate that most industries have fulfilled the basic principles of CPKB in accordance with BPOM RI Regulation No. 25 of 2019, particularly in terms of quality documentation, raw material control, facility sanitation, and personnel competency. However, several non-conformities were still identified, indicating that GMP implementation does not solely depend on written procedures, but also on the consistency of execution, supervision, and continuous evaluation.

The three companies demonstrated high levels of GMP compliance, with different characteristics of challenges identified. PT DEF faced the most complex challenges related to human resources, manual documentation, raw material variability, machine capacity, and environmental control. PT ABC experienced more constraints in terms of training, dependency on SOP preparation personnel, seasonal raw material variations, and environmental microbiological monitoring. Meanwhile, PT XYZ showed relatively minor issues, including the need for refresher training, SOP revisions, inconsistencies from new suppliers, and personnel traffic management. These differences indicate that GMP improvement strategies need to be tailored to the specific conditions of each company.

This study has several limitations. The number of respondents was relatively small, as the study only involved three responsible pharmacists from each cosmetic industry, meaning that the findings cannot yet be generalized to the entire cosmetic industry in Indonesia. The research instrument also used a self-report method, which may introduce respondent subjectivity bias and result in compliance scores that tend to be higher. In addition, this study did not include external audit data or direct observations as objective comparisons to validate the questionnaire and interview findings.

Pharmacist Roles and Responsibilities (Tupoksi) and GMP Implementation Based on the 4M + 1E Aspects

The analysis results indicate that pharmacists' roles and responsibilities are integrated across all 4M + 1E aspects in the implementation of GMP/CPKB in the three cosmetic industries. In the Man aspect, pharmacists play a role in competency development, GMP training, personnel discipline supervision, and evaluation of personal hygiene practices and the use of Personal Protective Equipment (PPE) (Paramita et al., 2025). In the Method aspect, pharmacists are involved in the

preparation, review, and control of SOPs, batch records, and the implementation of Good Documentation Practice to ensure documentation accuracy and consistency (Astuti et al., 2023).

In the Material aspect, pharmacists are responsible for monitoring the quality of raw materials and packaging materials through supplier qualification, specification verification, and storage control based on the FIFO/FEFO principles. In the Machine aspect, pharmacists' roles include validation, calibration, and maintenance of production equipment to ensure compliance with GMP standards (BPOM RI, 2023; Prayascita et al., 2020). In the Environment aspect, pharmacists contribute to sanitation control, production area zoning, and environmental monitoring to prevent cross-contamination. This integration of roles demonstrates that the high level of GMP compliance in the three industries cannot be separated from the active involvement of pharmacists in comprehensive quality system control.

CONCLUSION

The conclusion of this study shows that GMP/CPKB implementation at PT ABC, PT DEF, and PT XYZ was categorized as very good, with compliance levels ranging from 97.6% to 99.2% based on the questionnaire results. Pharmacists' roles and responsibilities were involved in all 4M + 1E aspects, including personnel development (Man), SOP and documentation control (Method), raw material supervision (Material), equipment validation and maintenance (Machine), as well as production sanitation and environmental monitoring (Environment). However, the interview results and fishbone analysis still identified several operational non-conformities, indicating that GMP/CPKB implementation does not only depend on the availability of a quality system but also on the consistency of implementation and supervision in practice.

This study has limitations due to the relatively small number of respondents and the use of a self-report method, which may introduce subjective bias. Future studies are recommended to involve a larger number of cosmetic industries, use objecti ve indicators such as quality audits or field observations, and apply a longitudinal approach to evaluate GMP/CPKB implementation continuously.

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