Analysis of Risk Minimization Strategies in the Implementation of Good Manufacturing Practices Through the Integration of FFMEA and AHP

Siti Asmaul Mustaniroh[1*], *Widya Dwi Rukmi* Putri[2], and *Muhammad Farras* Azhari[1]

[1]Department of Agroindustrial Technology, Faculty of Agricultural Technology, Universitas Brawijaya, 65145 Veteran St. Malang, East Java, Indonesia
[2]Department of Food Science and Biotechnology, Faculty of Agricultural Technology, Universitas Brawijaya, 65145 Veteran St. Malang, East Java, Indonesia

Abstract. The high milk production in East Java offers opportunities for SMEs to innovate and add value through dairy processing. Implementing Good Manufacturing Practices (GMP) is crucial for improving quality, competitiveness, and risk reduction. This study analyzes risk levels and strategies to minimize them using FFMEA and AHP methods, focusing on 14 GMP aspects based on BPOM RI Regulation No. HK.03.1.23.04.12.2206 (2012) in SMEs "X" and "Y". Findings reveal that three GMP aspects—buildings and facilities, product recall, and record-keeping—are not fully implemented. In SME "X", the highest risks stem from poor employee health (FRPN 0.915), low SME reputation (FRPN 0.859), and poorly recorded financial report administration (FRPN 2.365). In SME "Y", major risks arise from low SME reputation (FRPN 4.018) and production processes not meeting standards (FRPN 1.542). To mitigate these risks, recommended strategies include routine cleaning of the production area, establishing SOPs for product recalls, fast handling of returned goods, employee training on record-keeping, and regular internal audits.

1 Introduction

The production of milk in Indonesia, particularly in East Java, has been steadily increasing each year. One of the regions in East Java with the highest milk production is Batu, a city renowned for its tourism. According to data from the Indonesian Central Statistics Agency (BPS) in 2022, Batu City recorded the highest milk production in East Java, amounting to 25,322,017 kg. The significant level of milk production in Batu offers a fertile ground for industry players, particularly small and medium enterprises (SMEs), to innovate and develop milk-based processed products. This potential for innovation is underscored by the increasing consumer demand for diverse dairy products, which can enhance the added value of local milk production. SMEs "X" and "Y" are enterprises in Batu that operate in the food processing sector, to innovate and develop milk-based processed products with one of their products being milk candy. The production process is inherently subject to various risks that

* Corresponding author: asmaul_m@ub.ac.id

can disrupt the smooth operation of production and affect the final product quality. These risks may include non-conforming raw materials, equipment failure, or human error, which can lead to financial losses and a decline in product quality. Risk management is a critical component in the food processing industry, particularly to mitigate potential problems in the production process Risk is characterized an uncertain factor that can potentially hinder a company from achieving its objectives. Although it is impossible to eliminate all risks, appropriate measures can significantly minimize their impact, which is a fundamental aspect of operational efficiency in any production environment [1].

GMP serves as a crucial reference standard for the food processing industry to ensuring that the production process adhere the to the necessary uality and food safety criteria. The implementation of GMP is essential for maintaining high standards in food production, as it provides a structured framework that guides manufacturers in producing safe and high-quality food products. This framework is vital for compliance with regulatory requirements and for fostering consumer trust in food safety [2]. The importance of GMP is further emphasized by the findings of Lebanova et al., who analyzed non-compliances identified during GMP inspections. Their study highlights that adherence to GMP regulations is integral to a pharmaceutical manufacturer's quality management system, ensuring that products are consistently manufactured to quality standards appropriate for their intended use. This principle is equally applicable to the food processing sector, where the stakes of food safety are paramount.

The implementation of Good Manufacturing Practices (GMP) in small-scale dairy processing industries in developing countries is increasingly recognized as a critical factor for enhancing product safety and competitiveness. Recent trends indicate a growing emphasis on training and capacity building among smallholder dairy farmers and processors, which is essential for improving compliance with GMP standards and can significantly enhance food safety in smallholder settings [3]. This aligns with the broader trend of integrating training programs into GMP implementation strategies, which not only improves product quality but also fosters a culture of safety among producers. Moreover, the adoption of GMP practices is closely linked to market access and competitiveness for small and medium-sized enterprises (SMEs) in the dairy sector. Improved compliance with GMP standards enables these enterprises to meet international quality and safety requirements, thereby enhancing their marketability both domestically and internationally. The ability to produce safer and higher-quality products can lead to increased consumer trust and loyalty, which are vital for sustaining competitive advantage in a crowded marketplace [4].

Many SMEs lack awareness of GMP standards and the benefits associated with compliance, which can lead to a reluctance to adopt these practices [5]. Another significant barrier is the cultural and operational mindset within SMEs. Resistance to change is common, particularly in traditional sectors like dairy processing, where established practices may not align with modern GMP standards. This resistance can stem from a lack of understanding of the long-term benefits of GMP compliance, such as improved product safety and market competitiveness [4]. Furthermore, the high turnover rates of staff in SMEs can disrupt the continuity of training and adherence to GMP protocols, making it challenging to maintain consistent quality and safety standards [3]. In terms of risk minimization in food processing industries, SMEs often adopt several strategies to manage potential hazards associated with food safety. The analysis of risk minimization strategy formulation in the implementation of GMP can be reviewed from several GMP aspects based on the Regulation of the Head of the Indonesian Food and Drug Supervisory Agency (BPOM) No. HK.03.1.23.04.12.2206 of 2012 regarding Good Manufacturing Practices for Home Industries (CPPB-IRT). There are 14 aspects or variables used, namely production location and environtment, buildings and facilities, production equipment, water supply, hygiene sanitation facilities and activities, employee health and hygiene, hygiene sanitation maintenance and programs, storage, process

control, food labeling, supervision by the person in charge, product recall, record-keeping and documentation, employee training.

Problems in GMP compliance regarding to building and facility conditions, product recall standards, and record-keeping processes have not been sufficiently addressed in previous research. This study aims to plug this gap by offering a thorough examination of these important factors and providing practical risk-reduction strategies. The application of Failure Mode and Effects Analysis (FFMEA) and Analytic Hierarchy Process (AHP) in food safety and risk management has gained traction in recent years, particularly in the context of enhancing food safety protocols and improving compliance with Good Manufacturing Practices (GMP). These methodologies provide structured approaches to identify potential risks and prioritize them based on their impact and likelihood, which is crucial for SMEs in the dairy sector. One notable study that applied FFMEA in food safety is by Safitri et al., which developed a framework for assessing food safety hazards in primary production systems. This study emphasizes the importance of identifying critical control points and potential failure modes in food processing, thereby facilitating better risk management strategies [6]. Similarly, the integration of AHP in food safety risk assessment allows for a systematic prioritization of risks based on various criteria, such as severity and occurrence, which can significantly enhance decision-making processes in SMEs. Furthermore, the combination of FFMEA and AHP has been explored in various contexts to improve food safety outcomes. Despite several studies examining risk management in food processing using FMEA and AHP [7], limited research has integrated FFMEA and AHP specifically for assessing GMP implementation in SMEs, particularly in the dairy processing sector in Indonesia. Risk management frameworks play a pivotal role in enhancing GMP compliance among SMEs. By adopting a systematic approach to risk assessment and management, SMEs can identify vulnerabilities in their operations and implement targeted interventions to mitigate these risks. By utilizing tools like FFMEA and AHP, SMEs can prioritize their investments in training, equipment, and process improvements, leading to enhanced GMP compliance and overall operational efficiency. However, [8] does not specifically discuss the application of FFMEA and AHP in research..

By adhering to GMP guidelines, small-scale processors can minimize waste, reduce the risk of contamination, and improve resource efficiency. This is particularly relevant in the context of developing countries, where resource constraints often challenge food safety efforts. The integration of sustainable practices within GMP frameworks can lead to long-term benefits for SMEs, including cost savings and improved environmental performance. While the reference regarding food waste and loss prevention [9] does not directly support the claims made about GMP compliance, it does highlight the importance of efficiency in production processes, which is relevant to the discussion of operational improvements in SMEs.

In this study, the identification of risk events focused on GMP aspects with an implementation level of less than 80% (not categorized as good), rather than overall implementation. Based on the assessment from field observations, it was found that the issues in GMP implementation at SMEs "X" and "Y" were related to building and facility aspects, product recall, as well as record-keeping and documentation, which were not yet in compliance. To address these issues, the methods used include Fuzzy Failure Mode and Effect Analysis (FFMEA) and Analytical Hierarchy Process (AHP).

FMEA is used to identify potential failure modes with a priority scale and can gather data for decision-making and risk control [7]. The outcome of this method is a Risk Priority Number (RPN), obtained from the calculation of severity, occurrence, and detection (SOD). However, a notable disadvantage of this method is that it may yield identical Risk Priority Number (RPN) values for different failure modes, complicating the prioritization of risks. This challenge is highlighted by [1], to enhance the risk prioritization process, the integration

of FMEA with fuzzy logic has been proposed, resulting in the development of Fuzzy RPN (FRPN).

According to [10], fuzzy logic is a method to handle uncertainty. Once potential risks are identified, risk minimization strategies are determined using AHP. According to [11], AHP is a multi-criteria decision-making method that assigns weights to criteria and priorities alternatives in a structured manner based on pairwise comparisons. AHP is a structured technique that aids in decision-making by organizing and prioritizing complex problems, allowing for the effective allocation of resources to mitigate identified risks. This systematic approach ensures that risk management strategies are both effective and aligned with organizational objectives [12].

This study analyzes the risks in GMP implementation by considering 14 aspects as per BPOM regulations. The methods used are FFMEA to determine risk priorities, integrated with AHP to identify risk minimization strategies. The results of this study are expected to assist SMEs "X" and "Y" in addressing risks arising from the incomplete implementation of GMP. The objectives of this study are to analyze the performance of SMEs "X" and "Y" in GMP implementation, to assess the risk priority levels in GMP implementation based on FRPN, and to determine the appropriate risk minimization strategies for the non-compliant aspects of GMP implementation.

2 Research method

2.1 Research procedurs

The study was conducted at SMEs "X" and "Y", and data processing was carried out at the Agribusiness Management Laboratory, Department of Agricultural Industrial Technology, Faculty of Agricultural Technology, Universitas Brawijaya, Malang. SMEs "X" and "Y" were selected based on their active participation in the dairy processing industry in Batu, their compliance history with GMP standards, and their willingness to share operational data, thus representing typical SMEs in this sector.

The research procedures were systematically designed to achieve the research objectives. The study began with a preliminary survey and literature review, problem formulation, objective setting, determination of variables and respondents, risk identification, where expert opinions were collected from a panel of qualified industry professionals and academic researchers with extensive experience in food safety, GMP, and risk management. The selection criteria for these experts included a minimum of 5 years of relevant experience, academic qualifications in food technology or related fields, and active involvement in risk assessment projects. The experts were invited to complete structured questionnaires to provide input for both the FFMEA and AHP analyses**.** Subsequently, the study proceeded with risk identification, GMP data processing and analysis, FFMEA risk data processing and analysis, AHP mitigation data processing and analysis, and concluded with drawing conclusions and making recommendations.

2.2 Good manufacturing practices

The evaluation results of GMP implementation were analyzed using the gap analysis method which assesses the difference between the actual conditions and the ideal standards required for food safety and quality. This analysis underscores the necessity for continuous improvement in manufacturing processes to meet regulatory expectations and enhance product safety [8]. The results of the gap analysis method provided a quantitative percentage regarding the level of compliance and non-compliance with GMP implementation at SMEs

"X" and "Y". The quantitative percentage results were categorized into four classifications as follows:

1. Good category if the total compliance is >80%.
2. Moderate category if the total compliance is between 65-80%.
3. Poor category if the total compliance is between 50-65%.
4. Bad category if the total compliance is <50%.

Each aspect was calculated in the same way, revealing the percentage of GMP implementation for each aspect. Aspects with results <80% or not categorized as good were further analyzed for risk, as they were considered potential threats to the food safety of the produced goods.

2.3 Data processing with fuzzy failure mode and effect analysis

FFMEA was used to rank risks from highest to lowest based on the FRPN values, so that appropriate minimization strategies could be determined based on the highest risks. Risk assessment was conducted using three factors: severity (S), occurrence (O), and detection (D). Severity refers to the impact or level of severity caused by the occurrence of a risk. Occurrence refers to the frequency or how often the risk may occur. Detection refers to the ease with which a risk can be detected. These values were obtained from expert respondents' assessments on questionnaires. The SOD factors were translated into linguistic terms and fuzzy numbers. The final result was an FRPN, where the highest FRPN value in GMP aspects with compliance <80% became the risk priority for determining risk minimization strategies.

2.4 Data processing with analytical hierarchy process

AHP was employed to determine the priority risk minimization strategy based on the weights calculated from pairwise comparisons. Improvement alternatives were determined based on the selected criteria or variables with the highest risk. The hierarchy of GMP implementation risk minimization strategies consisted of three levels as follows:

1. The first level pertains to the goal to be achieved in the AHP calculation, which is the determination of the GMP implementation risk minimization strategy.
2. The second level pertains to the criteria or variables from GMP aspects with compliance levels <80%.
3. The third level pertains to the alternatives considered in determining the GMP implementation risk minimization strategy.

The highest value would be used to determine the alternative strategy for minimizing identified risks. A consistency test was necessary to calculate the Consistency Ratio (CR). The CR is a ratio between the Consistency Index (CI) and the Random Index (RI), which indicates how consistent the pairwise comparisons are relative to random comparisons. If the CR value is > 0.10, the root cause of the issue should be identified and the assessment corrected. If the CR value is $\leqslant$ 0.10, the assessment is considered accurate and consistent [13].

3 Result and discussion

3.1 GMP implementation analysis

The assessment of GMP implementation at SMEs "X" and "Y" across 14 aspects was conducted using the gap analysis method, by calculating the percentage of implementation and categorizing it based on the resulting values. The GMP assessment results for SMEs "X"

and "Y" are presented in Table 1. Based on this assessment, SME "X" achieved an overall implementation level of 85.094% with a "Good" category, while SME "Y" achieved an overall implementation level of 88.926% with a "Good". However, there are 3 out of 14 aspects that did not achieve the good category due to an implementation level ⩽80%.

Table 1. GMP assessment result

No	Aspects	SME "X"		SME "Y"	
		Implementations level (%)	**Category**	**Implementations level (%)**	**Category**
1	Production location and environtment	100	Good	100	Good
2	Buildings and facilities	**71,875**	**Moderate**	87,5	Good
3	Production equipment	100	Good	85,714	Good
4	Water supply	100	Good	100	Good
5	Hygiene sanitation facilities and activities	84,21	Good	100	Good
6	Employee health and hygiene	87,5	Good	100	Good
7	Hygiene sanitation maintenance and programs	85,714	Good	92,857	Good
8	Storage	90	Good	80	Good
9	Process control	100	Good	88,889	Good
10	Food labeling	100	Good	100	Good
11	Supervision by the PIC	85,714	Good	100	Good
12	Product recall	**50**	**Poor**	**50**	**Poor**
13	Record-keeping and documentation	**40**	**Bad**	**60**	**Poor**
14	Employee training	100	Good	100	Good
Total Implementation		**85,094**	**Good**	**88,926**	**Good**

3.2 Risk identification in GMP implementation

Risk identification in GMP implementation at SMEs "X" and "Y" was conducted through preliminary survey observations, interviews, and discussions with expert respondents. The identified risk components include risk events and risk agents in GMP implementation. The risk identification in GMP implementation at SMEs "X" and "Y" can be seen in Table 2.

Table 2. Risk identification

Variable	Risk Event	Risk Agent
Buildings and facilities	Dirty and dusty production area	Non-compliance and adherence in routine sanitation of the production area
	Poor employee health and productivity	
	Cross-contamination of products	Production layout does not comply with industry standards
Product recall	Low repotation of the SME	Lack of product supervision during the production process and in the market
	Compromise of customer safety and health	
	Non-compliance with applicable regulations	
Record-keeping and documentation	Production process not meeting standards	Low supervision during the production process
	Lack of planning in the production process	Fluctuating market demand
	Poorly documented financial reports	Limited administrative management
	Inadequate productuin record-keeping	

3.2.1 Risk identification of building and facilities variable

Non-compliance and inadequate adherence in routine sanitation of the production area can lead to the accumulation of dirty and dust creating an unsanitary environment. This risk is particularly pronounced when GMP are not properly implemented, specifically concerning the cleanliness of facilities such as walls, ceilings, doors, windows, and ventilation systems. As highlighted by Lebanova et al. [8], failure to maintain these areas can result in the buildup of contaminants that pose a threat to product safety. A production area that is not regularly cleaned will inevitably gather dust and dirt, which can compromise the quality of both the equipment and the food products being processed. Consequently, this contamination can significantly reduce the overall safety and quality of the final products, emphasizing the critical need for strict adherence to GMP standards in food production environments.

Employee health and productivity may be at risk due to non- compliance and adherence in routine sanitation practices in production areas. This risk exacerbated by failures in adhering in GMP implementation, particularly concerning the cleanliness of facilities such as walls, ceilings, and ventilation systems that remain unclean and are not routinely sanitized. According to [8] discusses non-compliances identified in GMP inspections, it does not specifically address the direct impact of a dirty environment on employee health issues such as respiratory problems and allergies.A production layout that does not comply with industry standards can can significantly increase the risk of cross-contamination in products. Cross-contamination refers to the transfer of bacteria or contaminants from one area to another, which can occur when Good Manufacturing Practices (GMP) are not properly implemented. Cross-contamination is the transfer of bacteria or contaminants from one area to another, which can occur when GMP are not properly implemented. Specifically, non-linear and crisscrossed material flows within a facility can exacerbate this risk, as highlighted by [6] who emphasize the importance of maintaining proper workflow to prevent contamination. In the food industry, cross-contamination can occur from one process to another if workstations are not separated or have a non-linear workflow in the food industry. Consequently, an irregular layout not only elevates the chances of contamination from foreign objects or microorganisms but also diminishes overall product quality and safety [8].

A production layout that does not comply with industry standards can significantly increase the risk of cross-contamination in products. Cross-contamination refers to the transfer of bacteria or contaminants from one area to another, which can occur when Good

Manufacturing Practices (GMP) are not properly implemented. Specifically, non-linear and crisscrossed material flows within a facility can exacerbate this risk, as highlighted by [6], who emphasize the importance of maintaining proper workflow to prevent contamination. In the food industry, inadequate separation of workstations can lead to cross-contamination between processes, resulting in unsafe products. Consequently, an irregular layout not only elevates the chances of contamination from foreign objects or microorganisms but also diminishes overall product quality and safety [8].

3.2.2 Risk identification of product recall variable

Lack of product supervision during the production process and in the market can negatively impact the reputation of SMEs. This risk arises from non-conformity in GMP implementation, specifically the absence of Standard Operating Procedures (SOPs) related to product recalls. According to Moratti et al. [1], poorly supervised products can lead to the circulation of defective or low-quality items, which diminishes consumer trust. When consumers receive inconsistent quality products, they may lose confidence in the SME, resulting in decreased sales and reduced likelihood of repeat purchases, as highlighted by Gorordo et al. [12]. This can directly harm the SME's reputation in the eyes of the public and business partners. Damage to the brand image can lead to long-term losses due to the erosion of customer loyalty and difficulties in attracting new consumers [14]. Insufficient supervision can also threaten consumer safety and health particularly when there is non-conformity in Good Manufacturing Practices (GMP) implementationThe absence of Standard Operating Procedures (SOPs) related to product recalls can exacerbate these risks, as highlighted by Lebanova et al, who emphasize the importance of rigorous monitoring during production. Products that are not rigorously monitored during production are at risk of contamination, leading to potential health issues for consumers, including food poisoning and other serious conditions. Furthermore, [15] discussed, how enhanced monitoring systems can mitigate these risks by ensuring compliance with safety standards. Ultimately, the lack of proper oversight in production processes can significantly compromise consumer health and safety [8].

Non-compliance with applicable regulations is another risk that arises from inadequate product supervision. This risk is associated with non-conformity in GMP implementation, specifically the absence of SOPs related to product recalls. Governments enforce various regulations and standards that producers in the food industry must follow to ensure product safety and quality, that discuss the importance of compliance with food safety regulations to mitigate risks associated with food production. Furthermore, [8] emphasize that adherence to Good Manufacturing Practices (GMP) is essential for maintaining high quality and safety standards in food products. Additionally, the study by [3] illustrates how training interventions can enhance compliance with safety standards among producers, thereby improving overall food quality and safety outcomes. Failure to report problematic product recalls to the authorities may result in the company being subject to penalties, including fines, business license revocation, or temporary or permanent operation bans,as highlighted by [15], who discuss the regulatory implications of non-compliance in the medical product sector.

The long-term impact of enalties for non-compliance with industry standards can lead to significant financial losses, loss of market share, and threats to the company’s business continuity, that discuss the consequences of regulatory failures in the pharmaceutical sector that can adversely affect operational stability and profitability.

3.2.3 Risk identification of record-keeping and documentation variable

Low supervision during the production process can lead to the risk of non-compliance with production standards. This risk is identified based on the non-compliance in the implementation of GMP, specifically the absence of records related to standard specifications for raw materials and the production process. Without supervision, SOPs may not be properly followed, leading to discrepancies in the final product specifications. Low supervision can result in the use of raw materials that do not meet the specified standards, thereby producing products that fail to meet the expected quality standards. According to [8], supervision in production processes is crucial to ensure that the products meet the established standards as effective oversight helps identify and rectify non-compliance with Good Manufacturing Practices (GMP), thereby safeguarding product quality and safety. Monitoring raw materials ensures that they meet the specified criteria, thus maintaining the consistency and quality of the final productas highlighted by [6], who emphasize the importance of rigorous quality assessments in food safety. This process is crucial in preventing contamination and ensuring compliance with Good Manufacturing Practices (GMP) [8].

Fluctuating market demand can lead to the risk of unplanned production process, resulting in an imbalance between production output and market needs. This risk arises from the non-compliance in the implementation of GMP, specifically the lack of records related to the final products, leading to uncertainty about the existing stock. When demand surges suddenly, SMEs may struggle to fulfill orders on time, causing delays and customer dissatisfaction while, a drastic decline in demand can lead to overproduction, causing stockpiling and potential financial losses [1, 12, 16].

Limited administrative management in SMEs can lead to risks related to financial report recording. This risk stems from the non-compliance in the implementation of GMP due to the absence of accurate and up-to-date financial records and documentation. When financial records are missing or poorly managed, SMEs may fail to track income and expenses accurately, leading to errors in budget planning and financial decision-making as highlighted by [17], who discuss the implications of inadequate financial oversight in operational contexts.The separation between business and personal finances is also frequently neglected by SME operators, leading to challenges in accurately identifying profits due to the mixing of personal income and expenses with business cash flow, as highlighted by the findings of [3].

Limited administrative management also impacts production record-keeping. This risk is derived from the non-compliance in the implementation of GMP due to the lack of accurate and up-to-date production records and documentation. Inadequate record-keeping results in unavailable data on raw material usage, machinery and equipment, and production output. Without accurate records, SMEs cannot effectively monitor raw material usage, leading to waste and shortages during production, which can ultimately compromise the quality of the final product due to deviations in material standards.

Production records are essential for tracking and evaluating production results, as they provide critical data that helps small and medium enterprises (SMEs) meet customer demand and plan future production effectively [1]. Without proper documentation, SMEs may struggle to maintain operational efficiency and respond to market needs, leading to potential losses in productivity and customer satisfaction [12]. The absence of accurate records can hinder decision-making processes, making it difficult for businesses to identify trends and areas for improvement [16]. Therefore, maintaining comprehensive production records is vital for the sustainability and growth of SMEs in a competitive market. Ultimately, effective documentation practices contribute to better resource management and enhanced overall performance.

3.3 Risk assessment using FFMEA

The risk assessment of GMP implementation is conducted using the FFMEA method by evaluating the factors of severity (S), occurrence (O), and detection (D). This assessment is based on the opinions of expert respondents through a questionnaire. Each identified risk event will be calculated to obtain the FRPN. The risk events with the highest FRPN in each variable will be prioritized for alternative risk minimization strategies. The risk assessment can be seen in Table 3.

Table 3. Risk assessment using FFMEA

Code	Risk Event	SME "X"		SME "Y"	
		FRPN	**Category**	**FRPN**	**Category**
	Risks for the Buildings and Facilities Variable				
A1	Dirty and dusty production area	0,634	Very Low (VL)	-	-
A2	Poor employee health and productivity	**0,915**	**Very Low (VL)**	-	-
A3	Cross-contamination of products	0,372	Very Low (VL)	-	-
	Risks for the Product Recall Variable				
B1	Low SME reputation	**0,859**	**Very Low (VL)**	**4,018**	**Low-Moderate (L-M)**
B2	Compromise of customer safety and health	0,434	Very Low (VL)	1,664	Very Low-Low (VL-L)
B3	Non-compliance with applicable regulations	0,218	Very Low (VL)	0,961	Very Low (VL)
	Risks for the Record-Keeping and Documentation Variable				
C1	Production process not meeting standards	0,627	Very Low (VL)	**1,542**	**Very Low-Low (VL-L)**
C2	Lack of planning in the production process	0,509	Very Low (VL)	1,290	Very Low-Low (VL-L)
C3	Poorly documented financial reports	**2,365**	**Low (L)**	0,381	Very Low (VL)
C4	Inadequate productuin record-keeping	1,106	Very Low (VL)	1,079	Very Low (VL)

3.3.1 Risk assessment of buildings and facilities variable

In SME "X", the risk event with the highest FRPN is poor employee health and productivity (A2). This risk event received an FRPN of 0.915 with a very low (VL) category. This risk is a primary concern that needs to be minimized to avoid disrupting the operational activities of SME "X". Risk A2 arises from non-compliance and inadequacy in the routine sanitation process of the production area. Cleanliness of the production area plays a crucial role in creating a healthy and comfortable work environment for employees.

Employees working in environments characterized by dirt and dust are at a heightened risk for various health issues, which can lead to significant distractions and concentration problem. Such conditions have been shown to adversely affect productivity and efficiency in the workplace, as the presence of airborne particulates can exacerbate respiratory problems and impair cognitive function [4, 18]. Based on GMP priorities, this risk is less suitable as a priority risk because employee health and productivity primarily affect the quality and

quantity of the produced products, without directly threatening food safety and consumer health. Risk A3 should be the priority risk due to its impact on food safety and consumer health. Therefore, addressing environmental cleanliness should be a strategic priority for organizations aiming to enhance workforce productivity and minimize health-related disruptions

3.3.2 Risk assessment of product recall variable

In SMEs "X" and "Y", the risk event with the highest FRPN is the low reputation of the SME (B1), with FRPN values of 0.859 and 4.018. This risk is a primary concern that needs to be minimized to prevent disruption to the operational activities of SMEs "X" and "Y". Risk B1 is caused by insufficient product oversight during the production process and in the market. This inadequacy allows defective products to circulate in the market and go undetected. The implications of such inadequacies are profound, as they can result in a loss of consumer confidence, ultimately affecting the long-term sustainability of businesses within the industry [8, 15]. Moreover, the relationship between product quality and market performance is well-documented, with studies indicating that a tarnished reputation due to quality issues can lead to significant declines in customer retention and sales figures [15]. Based on GMP priorities, this risk is less suitable as a priority risk because a low reputation mainly affects customer loyalty and does not directly threaten food safety and consumer health. Risk B2 should be the priority risk due to its impact on food safety and consumer health.

3.3.3 Risk assessment of record-keeping and documentation variable

In SME "X", the risk event with the highest FRPN is poorly recorded financial report administration (C3). This risk event received an FRPN of 2.365 with a the low (L) category. This risk is a primary concern that needs to be minimized to avoid disrupting the operational activities of SME "X". Risk C3 arises from limited administrative management. Poorly recorded financial reports can hinder to the SME's ability to accurately track income and expenses, , leading to errors in budget planning and financial decision-making, which are critical for maintaining operational efficiency and sustainability in small and medium enterprises. [8] focuses on non-compliances in GMP inspections and does not relate to the administrative management or financial reporting issues faced by SMEs.Based on GMP priorities, this risk is less suitable as a priority risk because it primarily affects the financial condition of the SME.

In SME "Y", the risk event with the highest FRPN is production processes not meeting standards (C1). This risk event received an FRPN of 1.542 with a very low-low (VL-L) category. This risk is a primary concern that needs to be minimized to avoid disrupting the operational activities of SME "Y". Risk C1 arises from inadequate oversight in the production process. This risk, primarily stemming from inadequate oversight in the production process, can lead to the utilization of substandard raw materials and non-compliantly with SOPs, ultimately resulting in products that fail to meet quality expectations [8] Based on GMP priorities, this risk should indeed be a priority due to its impact on food safety and consumer health. The significance of continuous monitoring and improvement of production processes is underscored by findings that highlight the prevalence of non-compliance in manufacturing operations, which can severely impact product quality and operational efficiency [8].

3.4 Determination of risk minimization strategies using AHP

Alternative risk minimization strategies are determined based on risk events with the highest FRPN values within each variable. The alternative risk minimization strategies are analyzed

using the Analytic Hierarchy Process (AHP). Based on the risk assessment results, risk minimization strategies can be formulated as shown in Table 4.

Table 4. Formulation of alternative risk minimization strategies

Goal	Variable	Risk	Code	Alternative
Risk Minimization in GMP Implementation	Buildings and facilities	Poor employee health and productivity	AA1	Routine cleaning of the production area
			AA2	Modification of production layout
			AA3	Improvement of the production environment
	Product recall	Low repotation of the SME	AB1	Creating SOPs related to product recalls
			AB2	Fast handling of returned goods
			AB3	Improvement of after-sales service
	Record-keeping and documentation	Production process not meeting standards Poorly documented financial reports	AC1	Employee training and development
			AC2	Routine internal audit
			AC3	Utilization of technology in production and record-keeping

Table 5. Respondent consistency ratio (CR)

No	Objective Criteria	SME "X"	SME "Y"
		Consistency Ratio	Consistency Ratio
1	Risk Minimization in GMP Implementation	0,069	-
2	Buildings and facilities	0,016	-
3	Product recall	0,060	0,089
4	Record-keeping and documentation	0,078	0,065

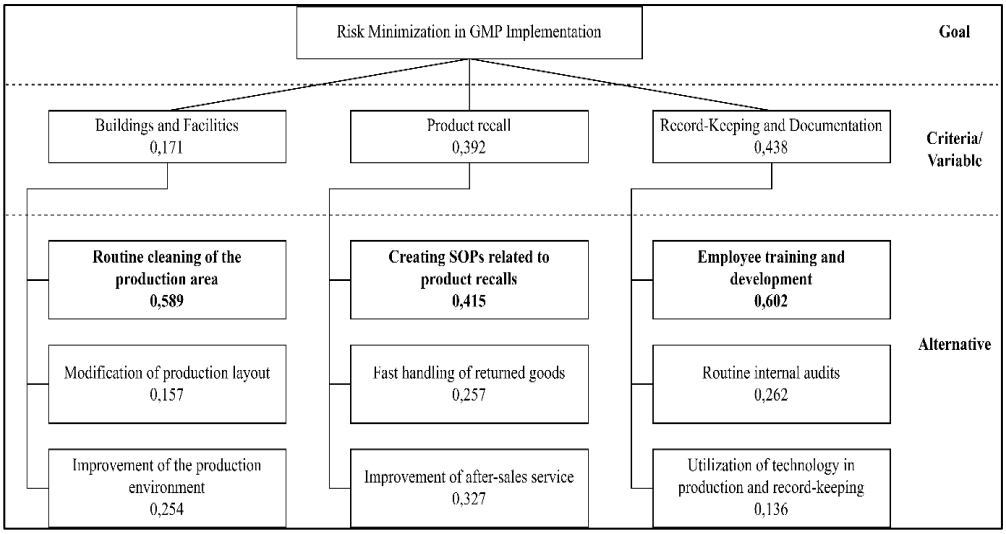

Fig.1. Hierarchical structure of risk minimization strategies in GMP implementation at SME "X"

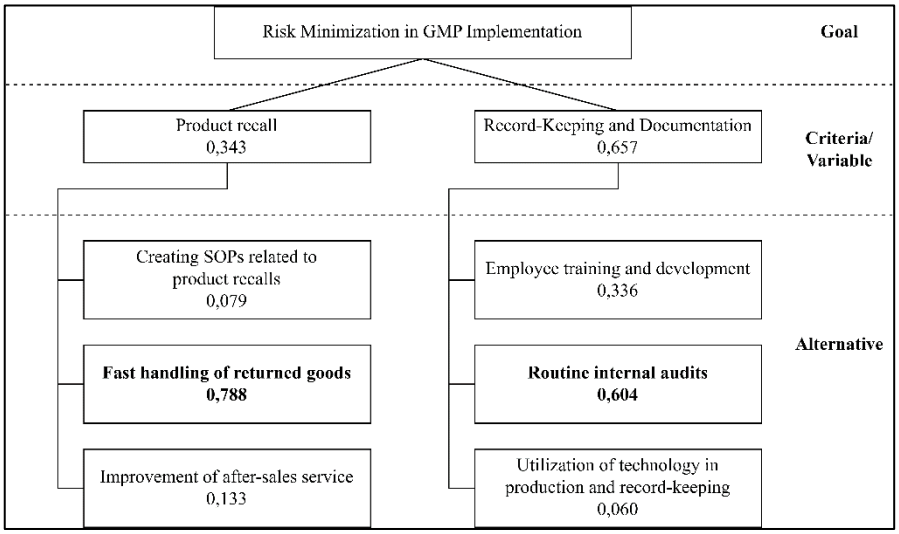

Fig. 2. Hierarchical structure of risk minimization strategies in GMP implementation at SME "Y"

Based on Table 5, the CR value is 0.069 for the goal of risk minimization in GMP implementation, the CR value is 0.016 for the buildings and facilities variable, the CR value is 0.060 and 0.065 for the product recall variable, and the CR value is 0.078 and 0.89 for the record-keeping and documentation variable. The calculation results show that the consistency value is below 0.10, which indicates that the calculation is consistent and can be considered good, so there is no need for recalculation.

The consistency ratio (CR) is a critical measure in decision-making processes, particularly in the context of analytic hierarchy processes (AHP). If the CR value is $\leqslant$ 0.10 (10%), it indicates a good and satisfactory consistency level, thus eliminating the necessity for recalculation of the decision matrix [12, 16].

According to [12, 16], if the CR value is $\leqslant$ 0.10 (10%), it indicates a good and satisfactory consistency level, thus eliminating the necessity for recalculation of the decision matrix. Meanwhile, if the CR value is $\geqslant$ 0.10 (10%) then the consistency level is not good in the pairwise comparison so that it is necessary to recalculate until the results are consistent. In addition to obtaining the CR value, the AHP calculation produces the weight of each criterion and alternative and the hierarchical structure which can be seen in Figures 1 and 2.

3.4.1 Minimization strategies of buildings and facilities variable

Based on Figure 1, the weight from the pairwise comparison of alternatives for the buildings and facilities variable at SME "X" shows that the highest priority alternative is routine cleaning of the production area (AA1), with a weight of 0.589. According to [4], routine cleaning of the production area is crucial for enhancing employee productivity, , as a clean and organized work environment significantly contributes to employee comfort and focus on their tasks. When the work environment is clean and well-maintaned, thereby allowing employees to perform their duties more efficiently and swiftly [6]. Furthermore, maintaining cleanliness fosters a positive work atmosphere, which is essential for boosting morale and motivation among employees [18]. The routine cleaning of the production area supports employees in achieving higher productivity and maintaining the quality of their work output. Ultimately, a hygienic work environment is vital for ensuring product quality and food safety as it mitigates risks associated with contamination and supports the overall effectiveness of production processes [19].

3.4.2 Minimization strategies of product recall variable

Based on Figure 1, the weight obtained from the pairwise comparison of alternatives for the product recall variable at SME "X" shows that the highest priority alternative is creating of SOPs related to product recalls (AB1) with a weight of 0.415. Developing SOPs for product recalls is crucial for maintaining consumer trust in the SME. According to [12], SOPs serve as essential framework and guide the execution of processes and tasks, ensuring consistency and compliance in operations. Specifically, a product recall SOP provides clear and structured instructions for SMEs to effectively identify, recall, and manage defective products thereby safeguarding consumer interests and maintaining product integrity [1] SMEs can respond quickly and effectively in addressing problematic products, thereby minimizing negative impacts on consumers. The ability of SMEs to respond swiftly to product issues is crucial in minimizing adverse effects on consumers which reflects their commitment to product quality and safety [16]. In addition to creating SOPs, a preventive measure that can be taken is enhancing audits during the production process, , as continuous monitoring can significantly reduce the incidence of defective products by ensuring adherence to established quality protocols [20]. Regular oversight ensures that equipment and raw materials are always in optimal condition, thus maintaining product quality consistency.

Based on Figure 2, the weights obtained from the pairwise comparison of alternatives for the product recall variable at SME "Y" shows that the highest priority alternative is fast handling of returned goods (AB2) with a weight of 0.788. Promptly handling returned goods is crucial for s SME to maintain their reputation and customer trust. When defective or non-compliant products, SME's not only demonstrate their commitment to quality and customer satisfaction but also mitigate potential consumer complaints that could adversely affect their image [4]. Moreover, effective management of product returns reinforces the perception of reliability and accountability among customers, which is critical for sustaining a positive brand reputation. This proactive approach in quality assurance fosters stronger customer relationships, ultimately protecting SMEs from the negative repercussions associated with unsatisfactory products [4, 21, 22].

3.4.3 Minimization strategies of record-keeping and documentation variable

Based on Figure 1, the weight from the pairwise comparison of alternatives for the recording and documentation variable at SME "X" shows that the highest priority alternative is employee training on record-keeping (AC1) with a weight of 0.602. Training employees in record-keeping enhance the quality of financial reports by equipping them with essential accounting techniques and the proficiency to utilize financial software effectively. . Employees can learn basic accounting techniques, how to use financial software, and the importance of meticulously recording every expense and income. This training fosters a comprehensive understanding of the critical nature of meticulous record-keeping, thereby raising awareness about the importance of accurate financial reporting, which is vital for organizational success and compliance with regulatory standards [3, 4].

Based on Figure 2, the weights obtained from the pairwise comparison of alternatives for the record-keeping and documentation variable at SME "Y" shows that the highest priority alternative is routine internal audits (AC2) with a weight of 0.604. Routine internal audits are essential to ensuring that the production process remains in line with established standards, as they allow small and medium-sized enterprises (SMEs) to promptly identify and rectify deviations before they escalate into significant issues. Regular audits, help maintain compliance with standard operating procedures (SOPs) among employees and facilitate the early detection of potential risks, thereby ensuring product quality and consistency in line with regulatory requirements [8].

Furthermore, these audits play a vital role in the overall quality management system by systematically addressing non-compliance issues identified during inspections, which is essential for maintaining the integrity of the manufacturing process [8]. Additionally, by implementing routine audits companies can effectively detection and mitigation of potential riskspreven defective products, and ensuring that all products meet the established quality standards and regulatory expectations [8].

4 Conclusions

The results of the study on risk minimization strategies in the implementation of Good Manufacturing Practices (GMP) at SMEs "X" and "Y" led to the following conclusions:

1. SMEs "X" and "Y" achieved overall GMP implementation rates of 85.094% and 88.926%, respectively, both categorized as good. However, there are 3 out of 14 aspects that have not been maximally implemented: buildings and facilities, product recall, and record-keeping and documentation.
2. The highest risks were identified for each variable. The priority risks at SME "X" are poor employee health and productivity (A2) with an FRPN of 0.915, low SME reputation (B1) with an FRPN of 0.859, and poorly recorded financial reports (C3) with an FRPN of 2.365. Meanwhile, the priority risks at SME "Y" are low SME reputation (B1) with an FRPN of 4.018 and production process ~~on~~ not meeting standards (C1) with an FRPN of 1.542.
3. Alternative risk minimization strategies were identified for each variable. The selected strategies for SME "X" are routine cleaning of production areas (AA1) with a weight of 0.415, creating SOPs related to product recall (AB1) with a weight of 0.602, and employee training on record-keeping (AC1) with a weight of 0.438. Meanwhile, the selected strategies for SME "Y" are the fast handling of returned goods (AB2) with a weight of 0.788 and routine internal audits (AC2) with a weight of 0.604.

5 Limitations and future research

This study is limited by its focus on only two SMEs in Batu, which may not fully represent the broader dairy processing industry in Indonesia. Future studies need to investigate other risk variables influencing GMP implementation and take advantage of a larger and more varied sample of SMEs. Additionally, more research could investigate into how the suggested risk minimization strategies affect operational effectiveness and conformance to food safety regulations over the long run. Additionally, more research could investigate into how the suggested risk minimization strategies affect operational effectiveness and conformance to food safety regulations over the long run.

6 Practical recommendations for SMEs

Based on our research, SMEs are advised to established up regular training programs and continuous internal review procedures in addition to implementing the suggested risk mitigation techniques into practice. SMEs can sustain high standards of product quality and safety while adjusting to new challenges in GMP compliance with the support of this proactive strategy.

References

1 M. Singh, N. Thakur, T.C. Nagaiah, High-performance alkaline battery-supercapacitor hybrid based on bimetallic phosphide/phosphate. Advanced Sustainable Systems. **9**, 1 (2024). https://doi.org/10.1002/adsu.202400705

2 H. Lebanova, S. Stoev, G. Petrova, Analysis of non-compliances identified in gmp inspections between 2013 and 2022. Pharmacia. **71** (2024). https://doi.org/10.3897/pharmacia.71.e120053

3 A. Beyene, S. Nigatu, J. Archila-Godinez, K. Amenu, B. Kowalcyk, D. Degefaw, A. Yousef, The impact of training intervention on levels of indicator bacteria and prevalence of selected pathogens in raw milk from smallholder women dairy farmers in central ethiopia. Journal of Food Protection. **88**, 2 (2025). https://doi.org/10.1016/j.jfp.2024.100446

4 K. Turner, C. Miree, A. Coppin, The role of human and social capital in achieving manufacturing objectives. Strategy and Leadership. **53**, 1 (2024). https://doi.org/10.1108/sl-02-2024-0011

5 S. Shayanmehr, S. Asumadu-Sarkodie, S.R. Henneberry, M.S. Sabouni, H. Mohammadi, R. Radmehr, E.K. Ofori, N.S. Foroushani, Market mechanisms and their role in sustainable food security: adapting to climate change in arid regions. Sustainable Futures. **9**, 100412 (2025). https://doi.org/10.1016/j.sftr.2024.100412

6 R. Safitri, E. Asselt, J. Müller-Maatsch, S. Vogelgsang, T. Dapcevic-Hadnadev, M. Nijs, Generic food safety assessment: a framework to evaluate food safety hazards emerging from change(s) in the primary production system–a case study involving intercropping. Journal of Food Protection. **87**, 11 (2024). https://doi.org/10.1016/j.jfp.2024.100371

7 P.S. Damanab, S.S. Alizadeh, Y. Rasoulzadeh, P. Moshashaie, S. Varmazyar, Failure modes and effects analysis (fmea) technique: a literature review. Scientific Journal of Review. **4**, 1 (2015). http://dx.doi.org/10.14196/sjr.v4i1.1805

8 H. Lebanova, S. Stoev, G. Petrova, Analysis of non-compliances identified in gmp inspections between 2013 and 2022. Pharmacia. **71** (2024). https://doi.org/10.3897/pharmacia.71.e120053

9 F. Economou, G. Chatziparaskeva, I. Papamichael, P. Loizia, I. Voukkali, J. Navarro-Pedreño, A. Zorpas, The concept of food waste and food loss prevention and measuring tools. Waste Management & Research the Journal for a Sustainable Circular Economy. **42**, 8 (2024). https://doi.org/10.1177/0734242x241237187

10 H. Thakkar, S. Vaishnavi, Y. Hiteshri, S. Manan, Comparative anatomization of data mining and fuzzy logic techniques used in diabetes prognosis. Clinical eHealth. **4** (2020). http://dx.doi.org/10.1016/j.ceh.2020.11.001

11 Y. Liu, C.M. Eckert, C. Earl, A review of fuzzy AHP methods for decision-making with subjective judgements. Expert Systems with Applications. **161**, 113738 (2020). https://doi.org/10.1016/j.eswa.2020.113738

12 E. Jang, H. Yu, E. Kim, J. Hwang, J. Yoo, J. Choi, S. Jang, The therapeutic effects of blueberry-treated stem cell-derived extracellular vesicles in ischemic stroke. International Journal of Molecular Sciences. **25**, 12 (2024). https://doi.org/10.3390/ijms25126362

13 W. Habsari, D. Taufik, U. Faqih, A. Yandra, A multi-criteria decision-making approach using ahp for pudak packaging supplier selection. Jurnal Teknologi Industri Pertanian. **32**, 2 (2022). https://doi.org/10.24961/j.tek.ind.pert.2022.32.2.197

14 P. Paduloh, K.M. Dyani, Sumanto, I.R. Rifda, Analysis of reverse supply chain performance in beef industry with the supply chain operation reference method. Jurnal

Teknologi Industri Pertanian. **30**, 3 (2020). http://dx.doi.org/10.24961/j.tek.ind.pert.2020.30.3.290

15 M. Gorordo, R. Rojas-Cortés, J. Carino, J. Zambrano, J. Castro, Alertas sanitarias de productos médicos subestándares, falsificados y no registrados al inicio de la pandemia de covid-19 en las américas. Revista Panamericana De Salud Pública. **48**, 1 (2024). https://doi.org/10.26633/rpsp.2024.7

16 H. Xiao, Z. Qin, B. Xu, M. Long, Q. Wu, X. Guo, W. Wu, Bacillus amyloliquefaciens b10 alleviates the immunosuppressive effects of deoxynivalenol and porcine circovirus type 2 infection. Toxins. **16**, 1 (2023). https://doi.org/10.3390/toxins16010014

17 F. Mück, F. Scotti, Q. Mauvisseau, B. Thorbek, H. Wangensteen, H. Boer, Three-tiered authentication of herbal traditional chinese medicine ingredients used in women's health provides progressive qualitative and quantitative insight. Frontiers in Pharmacology. **15** (2024). https://doi.org/10.3389/fphar.2024.1353434

18 M. Pakdel, A. Olsen, E. Bar, Towards sustainability: a case study on the integration of hygienic design and sustainability in norwegian meat processing facilities. Journal of Agriculture and Food Research. **19**, 101642 (2025). https://doi.org/10.1016/j.jafr.2025.101642

19 J. Renye, C. Chen, A. Miller, S. Lee, A. Oest, K. Lynn, J. Capobianco, Integrating bacteriocins and biofilm-degrading enzymes to eliminate l. monocytogenes persistence. International Journal of Molecular Sciences. **26**, 1 (2025). https://doi.org/10.3390/ijms26010399

20 M. Mizuno, K. Abe, T. Kakimoto, H. Hasebe, I. Sekiya, Decreasing electricity costs of clean room for cell products during non-operation. Regenerative Therapy. **26** (2024). https://doi.org/10.1016/j.reth.2024.11.002

21 Y. Bao, N. Buhay, Q. Zheng, A dynamic model for gmp compliance and regulatory science. Journal of Pharmaceutical Innovation. **19**, 3 (2024). https://doi.org/10.1007/s12247-024-09825-x

22 M. Belal, V. Shukla, S. Ahmad, S. Balasubramanian, Green pharma supply chain: a review of existing practices and future directions. Management of Environmental Quality an International Journal. **36**, 1 (2024). https://doi.org/10.1108/meq-08-2023-0249