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Evaluation of GMP Compliance on Cosmetics: Case Study on Cosmetic Industries in Indonesia

Rizka Ayu Kusuma Widjanarko[1], Yudo Anggoro[2]
School of Business and Management Institut Teknologi Bandung[1,2]
TK Low Center for Executive Education, Graha Irama (Indorama) 12th floor
Jl. HR. Rasuna Said Kav 1-2 Jakarta, 12950, Indonesia
Correspondence Email: rizka_widjanarko@sbm-itb.ac.id
ORCID ID: https://orcid.org/0000-0002-7229-8681

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ABSTRACT

The cosmetic industry has been designated as one of the priority sectors, as stated in the Master Plan of National Industry Development 2015-2035. The priority development programs in the cosmetic sector are mastering technology and building international standard manufacturing capabilities. The cosmetic industry's ability to comply with international standards, including good manufacturing practices (GMP), is mandatory, mainly since the ASEAN Harmonized Cosmetics Regulatory Scheme was fully implemented. It has been almost 14 years since the scheme's implementation, and the Indonesian FDA has enforced all stipulations within the scheme framework. This study aims to evaluate the policy impact of GMP compliance on cosmetic industries in Indonesia through a cost-benefit analysis. A qualitative descriptive method is conducted to identify the benefits and the costs of GMP compliance and determine the importance or significance of the benefits and costs components. The result findings showed the more significant cost components include maintenance of building and facilities, quality control, maintenance of equipment, and sanitation and hygiene. In comparison, the weight scores of the benefit components do not differ much, with the benefit of increased product sales being perceived to be the most important.

Keywords: Cosmetics Industry, Cost-Benefit Analysis, Good Manufacturing Practices, Indonesian FDA, SDG

JEL Classification: D61, D78, H1

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INTRODUCTION

The Market of Beauty Industry

The beauty industry—involving skincare, haircare, color cosmetics, fragrances, and personal care products—has become one of the most resilient industries over time. The sector has shown positive performance in responding to the economic crisis by having successfully bounced back in two years after being slightly impacted by the 2008 financial crisis. And once again, —despite having a pretty deep contraction in 2020 (-15 percent), the industry is projected a return to growth in 2022 and has shown a positive response to the crisis during the COVID-19 pandemic, as shown by several brands shifting their manufacturing to produce hand sanitizers and cleaning agents. (Gerstell et al., 2020) (Marchessou and Spagnuolo, 2021)

The cosmetics market in Indonesia, according to the Association of Indonesian Cosmetics Companies and Associations (PPAK Indonesia) in 2021, is projected to grow by around 7% to US$ 7.45 billion from US$ 6.95 billion in 2020. (Ayu, 2021) According to the Indonesian FDA, cosmetic products rank first in the total number of products registered for five years (2016-2020), with 201,301 notification numbers (53% amongst medicines, traditional medicines, health supplements, food, and beverages). The new application on cosmetics notification has an increasing trend from 2016-2020, mainly contributed by local cosmetics. During 2020, there were 45,114 local cosmetic notification numbers (-16.00% growth from 2019) and 28,468 for the import cosmetics (19.26% growth from 2019). It is a positive signal indicating that the production capacity of the local cosmetic manufacturing industry is growing significantly.

According to The Director-General of Small, Medium, and Multifarious Industries (IKMA) of the Ministry of Industry Republic of Indonesia, —Gati Wibawaningsih, the Indonesian cosmetic industry sector in 2020 grew significantly. The growth performance of the Chemical, Pharmaceutical, and Traditional Medicine Industries sector, which includes the cosmetics industry, increased by 9.39% in 2020 and contributed 1.92% to Indonesian Gross Domestic Product (GDP) (Gareta, 2021). Due to the potential of this industrial sector to the country's economy, the Government of the Republic of Indonesia has designated the cosmetics manufacturing industry as one of the priority sectors as stated in the Master Plan of National Industry Development Year 2015-2035. In the master plan, it is stated that the priority industrial development programs in the cosmetic sector include mastering technology and building international standard manufacturing capabilities (2015-2019) and facilitating the development and construction of a large-scale cosmetic industry with export orientation (2020-2035). (Ministry of Industry Republic of Indonesia, 2015)

ASEAN Harmonized Cosmetics Regulatory Scheme

The capability of the cosmetic industry in meeting international standards is mandatory, mainly since the ASEAN Harmonized Cosmetics Regulatory Scheme (AHCRS) was effective to be fully implemented starting January 1, 2008. In addition, AHCRS contains a Mutual Recognition Agreement, which harmonizes the regulation of cosmetics products across the region of ASEAN Member States. The objectives of the agreement are to enhance ASEAN Member States cooperation in ensuring safety, quality, and claimed efficacy of cosmetic products marketed in ASEAN; and to eliminate limitations on cosmetic products trade among the Member States through harmonization of technical requirements, mutual recognition of product registration agreements and adoption of the ASEAN cosmetics guidelines (ASEAN, 2003).

Within the framework of the AHCRS, the main aspect agreed upon was the shift from the "pre-market safety evaluation" registration system to a "post-market surveillance"

system for cosmetic products, which was felt to be more efficient and accommodate the growing needs of the cosmetic market. The preceding system was turned into a "notification system," in which the cosmetic industry or the party who will be responsible for distributing cosmetics on the ASEAN market shall notify the regulatory agency of the respective Member State prior to the product being circulated. To compensate for the simplification procedures of the pre-market approval system, the cosmetic industry or cosmetic notification applicants are required to be responsible for the safety, quality, and efficacy of their products. Therefore, compliance with good manufacturing practices (GMP) is mandatory. Article 3 of the Agreement on AHCRS stated that signatory Member States should undertake appropriate measures to adopt and implement the standard technical documents, one of which is the ASEAN Guidelines for Cosmetic Good Manufacturing Practice (GMP Guidelines). (The World Bank, 2008)

Cosmetics Industry in Indonesia

According to Regulation of the Minister of Health of Republic Indonesia No. 1175/MENKES/PER/VIII/2010 concerning cosmetics production license, the cosmetic industry is the industry that manufactures cosmetic products and has obtained an industrial business license or industrial registration license under the provisions of law and regulation in Indonesia. The cosmetic industries operated in Indonesia are categorized further based on the forms and types of cosmetic dosage form allowed to be manufactured, namely the A class cosmetic industry and B class cosmetic industry. The A class is granted rights to manufacture all forms and types of cosmetic dosage form, while the B class is granted rights to manufacture only certain dosage forms and types using modest technology.

Prior to registration submission to obtain cosmetics notification number, the cosmetic industry should obtain licenses related to GMP, so-called *Cara Pembuatan Kosmetik yang Baik* (CPKB certification), authorized by *Badan Pengawas Obat dan Makanan* (The Indonesian FDA). CPKB or GMP on cosmetic is defined as all aspects of cosmetic manufacturing operational activities that ensure the products are consistently manufactured and comply with the specified quality according to the intended use. Thus, GMP is a guideline that covers all aspects of production and quality control. The primary purpose of GMP compliance is to protect the public against unsafe and unstandardized cosmetic products that could be harmful to health. In addition, it can increase the added value and competitiveness of cosmetics products in the domestic and international markets.

Business Issues

It has been almost 14 years since the implementation of AHCRS. The Indonesian FDA has adjusted the cosmetic control system and enforced all stipulations within the framework of the agreement. Post-market surveillance control, particularly on monitoring GMP compliance, has been carried out by the Indonesian FDA through routine inspection by the headquarter and regional office. However, based on the results on inspection of production facilities —the cosmetics manufacturing industry, the implementation of GMP compliance is still inconsistent, as evidenced by the high inspection findings. Furthermore, most industries are still experiencing difficulties in taking appropriate corrective and preventive actions against inspection findings. To overcome these problems, the Indonesian FDA has been assisting the industry in taking proper corrective and preventive actions, publishing the guidelines on GMP implementation, providing learning materials, and conducting training on GMP. However, the Government has never assessed the impact of the policy on business actors, particularly the economic aspect of GMP compliance.

This study aims to evaluate the policy impact of GMP compliance on cosmetic industries in Indonesia through a cost-benefit analysis. This study is expected to identify the benefits perceived and the costs incurred due to the GMP compliance and determine the importance or significance of the benefits and costs components.

LITERATURE REVIEW

An approach of policy assessment through evidence-based policymaking is increasingly popular. Scientific theories and empirical evidence used as inputs to policy decisions make a lot of sense in creating better policies and regulations, both on ex-ante and ex-post. According to (Leuz, 2018), evidence-based policymaking is an effort to base policy decisions on scientific and empirical evidence, using methodologies as instances are impact studies, cost-benefit analysis, program evaluation, and academic research. The Presidential Instruction Republic of Indonesia, Number 7 of 2017 concerning Adoption, Supervision, and Control of Policy Implementation at the Level of State Ministries and Government Institutions, has obliged the preparation of impact analysis and public consultation in the preparation of regulations and policies that have a broad impact on the community.

One of the tools or approaches which can be used to improve the quality of government policies is Regulatory Impact Analysis (RIA). RIA is a systematic identification and assessment process of the expected impact of regulation, using consistent analytical methods, such as Cost-Benefit Analysis (CBA). The important contribution of RIA to the quality of policy decision-making is not judged by the accuracy of the calculations used but the act of analyzing-questioning, understanding real-world impacts, and exploring assumptions. RIA can be applied whether to propose a new policy or evaluate existing policies. (OECD, 2008)

There is an assumption that RIA can only be applied to economic policy, mainly because the CBA component is an essential part of the process. However, according to a study by (Kirkpatrick et al., 2004), such an assumption is incorrect. Many countries applied RIA for social and environmental policies as well (in addition to economic policy). Besides being considered that RIA can only be applied to economic policy, CBA is also considered as the most complicated part of the method process of RIA, and both of the cost and benefit parameters are considered to be valued in terms of money. However, this assumption is not entirely correct. In conducting RIA, it is plausible that essential benefits and costs cannot be quantified in terms of money. In such cases, a "partial" CBA can be performed. The results will still be helpful for decision-makers as it narrows the range of issues that must be addressed through a more subjective, qualitative analysis. Where costs are difficult to quantify, it is often possible to discuss them qualitatively and conclude their relative importance. Thus, a partial CBA can also improve decision-making. (Legal Bureau of Ministry of National Development Planning, 2011)

In conducting RIA, the data collected must be of high quality. One of the data collection strategies recommended by (OECD 2008) is surveys. Surveys by using well-designed questionnaires aim to obtain specific information about the policy parameters being evaluated. A designed survey of a representative group of parties affected by regulation can provide information on compliance costs and benefits. However, there are specific points to note relating to this method, including:

1. The target survey respondents are representatives of the parties affected by the policy being evaluated. Therefore, it is necessary to ensure that the respondent group meets the inclusion criteria.
2. The questionnaire is prepared realistically, which contains questions that the respondents can correctly interpret to answer adequately.

3. Sample size should be considered carefully.
4. Avoid posting questions that will result in biased answers. Direct interviews can be a consideration, mainly where compliance cost issues are complex.

RESEARCH METHOD

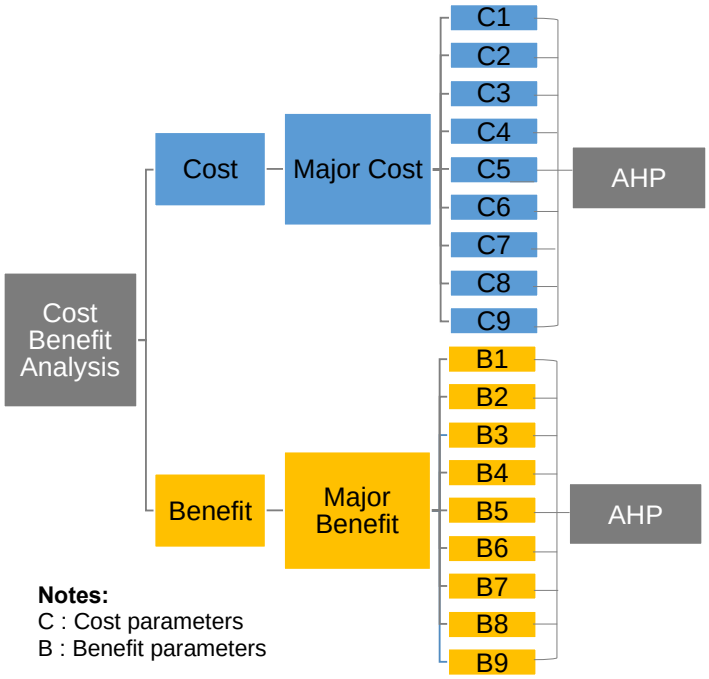
This research study used a qualitative cost-benefit analysis approach, using a survey as a method recommended by the Organization for Economic Co-operation and Development (OECD). The survey method was carried out using a questionnaire with the target respondents of the cosmetic industries in Indonesia. The questionnaire was sent with an official letter from the Indonesian FDA to the cosmetic industry associations, including the Association of Indonesian Cosmetics Companies (PERKOSMI), Indonesian Small and Medium Cosmetic Entrepreneurs Association (GP KOSKEMINDO), and Indonesian Cosmetics Entrepreneurs Association (PPAK Indonesia). The inclusion criteria of the target respondent is the A-class cosmetic industry. This A-class cosmetic industry is the cosmetic industry that is granted the right to produce all forms and types of cosmetic preparations, and therefore is obliged to implement the entire 12 (twelve) GMP aspects.

The questionnaire consists of several parts, as follows:

a. Part 1 respondent identity
b. Part 2 company information
   Questions include the value of the net asset, annual sales revenue, number of employees.
c. Part 3 analysis of costs significance
   Questions aim to compare the cost components incurred for each GMP operational activity in pairs (pairwise comparison) according to the level of costs significance.
d. Part 4 analysis of benefits importance
   Questions aim to compare the benefit components perceived by the implementation of GMP compliance in pairs (pairwise comparison) according to the level of benefits importance.

Data analysis was carried out using the analytical hierarchy process (AHP) method. The advantages of using the AHP method include evaluating complex situations to support decision-making by establishing important criteria for existing decisions and their relative relevance in ranking order. In addition, the weight of the criteria becomes more subjective according to the interests of decision-makers. Many studies have been conducted using the AHP method to decide the choice of various alternatives based on the weight of the criteria. (Kurniawati et al., 2021) (Siregar & Andiani, 2019) (Nuraeni, 2019) The decision model to identify and compare the cost and benefit components significance or importance is shown in Figure 1.

Figure 1. Decision Model of Qualitative Cost-Benefit Analysis



The cost and benefit parameters were adapted from research conducted by Anyakora et al. (2017), with adjustments to operational activities stated in Regulation of Indonesian FDA 31/2020 concerning guidelines for GMP on cosmetics (CPKB), in which these activities have the potential costs incurred. The components of major cost and major benefit coded as in Figure 1 are detailed in Table 1.

Table 1. Components of Major Cost and Major Benefit

Major Cost		Benefit-Cost	
C1	Employee Training	B1	Increased ability to access new markets or exports
C2	Maintenance of building and facilities	B2	Increased business expansion through contract manufacturing
C3	Maintenance of equipment	B3	Business diversification by producing household health supplies (disinfectant, hand sanitizer, detergent, etc.)
C4	Sanitation and hygiene	B4	Increased product sales
C5	Quality control	B5	Increased product shelf life
C6	Documentation	B6	Reduced risk of substandard raw materials or products (chemical, physical, and microbial)
C7	Internal audit	B7	Reduced customer complaints and product recalls (reject or recall)
C8	Storage	B8	Increasing the company's credibility and competitiveness
C9	Product complaint handling and product recall	B9	Inclusion in the Relaxation program and acceleration of licensing at the POM

The next step is the AHP process to derive the relative priorities (weights) for the components in pairs. Saaty (2012) has developed a numerical scale to compare the relative importance of each criterion with each other in pairs, as shown in Table 2.

Table 2. Saaty's Pairwise Comparison Scale

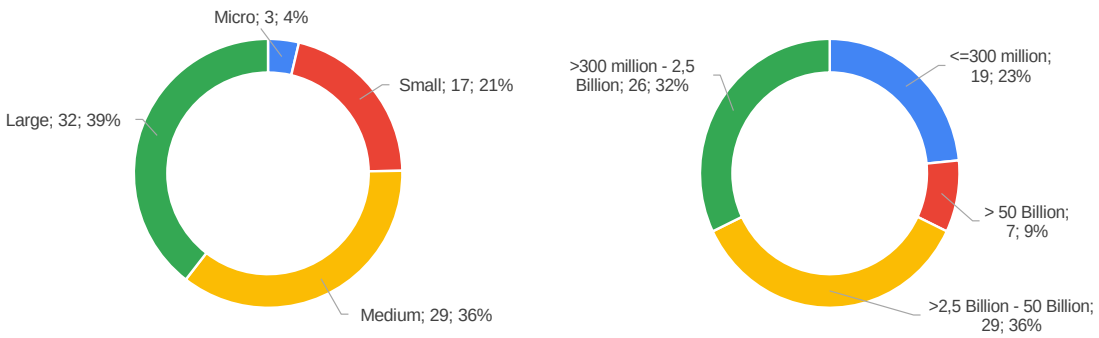
Verbal Judgment	Numeric Value
Extremely Important	9
	8
Very strongly more important	7
	6
Strongly more important	5
	4
Moderately more important	3
	2
Equally important	1

RESULTS AND DISCUSSION

Industry Profile

A total of 88 respondents representing the cosmetic industries in Indonesia participated in this survey. However, 81 cosmetic industries met the inclusion criteria. Seven respondents were excluded from the analysis because they did not meet the inclusion criteria: respondents from the B-class cosmetics industries and companies not registered as the cosmetic industry based on Indonesian FDA data. This number of respondents represents 14.97% of the total 541 A-class cosmetic industries in Indonesia. A-class cosmetic industry is inclusion criteria, as for the industry within this class is obliged to apply 12 (twelve) aspects of CPKB (quality management system, personnel, premises and facility,equipment, sanitation and hygiene, production, quality control, documentation, internal audit, storage, contract manufacturing and laboratory testing, handling complaints and product recalls). In comparison, class B only needs to apply 2 (two) aspects: sanitation and hygiene, and documentation. B-class cosmetics industry may also carry out operations as required by the other 10 (ten) aspects as for the A-class. Still, it may not be as comprehensive as them, so there is a possibility of bias in interpreting the costs incurring from operational activities that are not required.

Figure 2. Industry Profile Based on Net Asset (a) and Annual Sales Revenue (b)



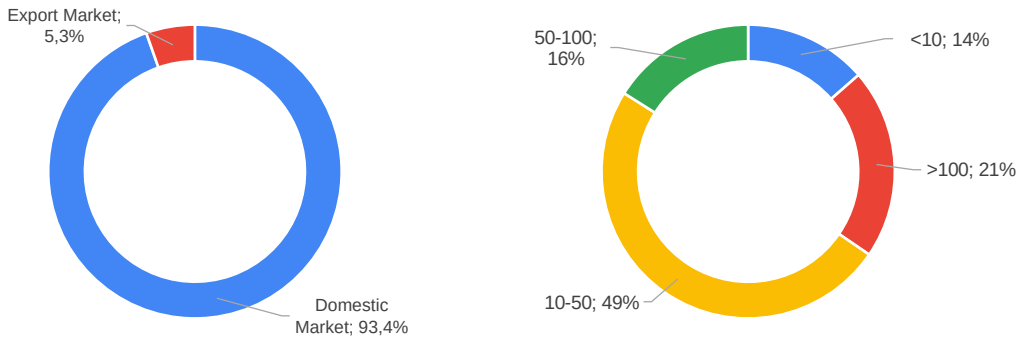
(a) (b)

Referring to Government Law of the Republic of Indonesia Number 20 the Year 2008 concerning Micro, Small and Medium Enterprises, the types of businesses are

categorized into Micro, Small, Medium, and Large Enterprises. This classification is based on net assets excluding land and buildings or annual sales revenue. In Figure 2, based on the net assets, industries included in the micro, small, medium, and large categories, respectively 4%, 21%, 36%, and 39%. Meanwhile, based on annual sales revenue, as many as 23% have annual sales revenue of ≤300 million IDR, 32% have annual sales revenue of >300 million – 2,5 Billion IDR; 36% have annual sales revenue of >2,5 billion – 50 billion IDR, and 9% have annual sales revenue of >50 billion IDR.

As depicted in Figure 3, the average market for domestic and export accounted for 93,4% and 5,3%. As of the 81 industries, 16 industries have expanded their market into exports. Based on the number of employees in production facilities, 14% of industries stated that they had <10 employees, 49% industries had 10-50 employees, 16% industries had 50-100 employees, and 21% industries had >100 employees.

Figure 3. Percentage of Domestic and Export Market (a) and Number of Employee in Production Facility (b)



(a) (b)

Cost Components Significance in Implementation of GMP Compliance

In the third part of the questionnaire, respondents were asked to compare the major cost components incurred in implementing GMP (C1-C9) in pairs (pairwise comparison) according to the level of significance of the costs incurred. The computational process and data analysis of the pairwise comparison was carried out using the Expert Choice version 11 software. The result for pairwise comparison is determined with the weighing rank score of each component, as shown in Table 3.

There are two groups of components based on the weight scores. The more significant cost components include maintenance of building and facilities, quality control, maintenance of equipment, and sanitation and hygiene. On the other hand, product complaint handling and recall, storage, employee training, internal audit, and documentation are less significant components.

Table 3. Weighing Rank Score for The Significant Cost Components of GMP Compliance

Major Cost		AHP Weighing rank score*
C2	Maintenance of building and facilities	0.192
C5	Quality control	0.173
C3	Maintenance of equipment	0.172
C4	Sanitation and hygiene	0.122
C9	Product complaint handling and product recall	0.084

Major Cost		AHP Weighing rank score*
C8	Storage	0.074
C1	Employee Training	0.069
C7	Internal audit	0.063
C6	Documentation	0.052

*Note: *) The higher, the more significance of cost incurred*

Respondents were also asked to identify operational activities that potentially incur costs in each aspect of GMP with optional and open-ended questions. The identification results show that within the more significant cost groups, the identified operational activities are quite complex, more varied, and have more potential in incurring costs. For instances in the maintenance of building and facilities, potential identified operational activities include air ventilation system maintenance (e.g., air filter replacement, purchase, and maintenance of dust collector if required); maintenance of building construction due to water leakage; Water treatment plan system, including maintenance of water filters used for production; pest control program; purchase and maintenance of temperature, pressure, time and humidity controllers; maintenance of drainage system; construction of new production facilities for new types of preparations.

Benefit Parameters Importance in Implementation of GMP Compliance

In the final part of the questionnaire, respondents were asked to compare the major benefits perceived in GMP implementation (B1-B9) in pairs (pairwise comparison) according to the level of importance. Based on the results of data processing with the Expert Choice version 11, the outcome for pairwise comparison of benefit components is determined with the weighing rank score of each component, as shown in **Table 4**. The weight scores of all benefit components do not differ much from each other, with the benefits from increased product sales being felt to be the most significant.

Table 4. Weighing Rank Score for The Important Benefit Components of GMP Compliance

Major Benefit		AHP Weighing rank score*
B4	Increased product sales	0.131
B6	Reduced risk of substandard raw materials or products (chemical, physical, and microbial)	0.114
B7	Reduced customer complaints and product recalls (reject or recall)	0.112
B3	Business diversification by producing household health supplies (disinfectant, hand sanitizer, detergent, etc.)	0.111
B1	Increased ability to access new markets or exports	0.110
B8	Increasing the company's credibility and competitiveness	0.108
B9	Inclusion in the Relaxation program and acceleration of licensing at the POM	0.107
B2	Increased business expansion through contract manufacturing	0.105
B5	Increased product shelf life	0.102

*Note: *) The higher, the more significance of cost incurred*

CONCLUSION

The result findings showed the more significant cost components of GMP compliance implementation in cosmetic industries in Indonesia include maintenance of building and facilities, quality control, maintenance of equipment, and sanitation and hygiene. In comparison, the weight scores of all benefit components do not differ much, with the benefits from increased product sales being perceived to be the most important.

It is necessary to conduct further studies related to quantitative benefit-cost analysis with the monetization of benefit and cost components incurred by the implementation of GMP compliance. The study will provide a more detailed description of the business processes in the cosmetic industry in implementing GMP. In addition, it is necessary to analyze the correlation between the results of the study in this study and the results of routine inspections carried out by the Indonesian FDA to monitor GMP compliance. Correlation is intended to see a relationship between cost burden and GMP non-compliance (inspection results).

The results of this study can provide an overview to the Indonesian FDA and other relevant government agencies in increasing assistance programs to the cosmetic industry regarding the implementation of GMP compliance. In addition, it can also provide an overview to the cosmetic industry in formulating a strategy for the effectiveness and efficiency of cosmetic manufacturing operations.

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DECLARATION OF CONFLICTING INTERESTS
The authors declare that they have no conflicting interests or personal relationships that might have appeared to influence the study result reported in this paper.

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