Abstract
Good manufacturing practices (GMP) can be considered as a regulated policies, codes or even guidelines that govern the operations of cosmetic, drugs, food, and medical devices manufacturers. Getting GMP certification is an industrial priority. Unfortunately, not many small and medium enterprises can successfully apply or renew the GMP manufacturing license. The GMP pre-operational costs requirements, employees’ lack of knowledge on GMP practices, lack of urgency and supervision by management are some of the obstacles in complying with the codes of GMP. This paper investigates a Malaysian manufacturer in goat’s milk based of body care, skin care, hair care, cosmetic products and food supplement industrial practices. The methodology includes individual and group interviews, and site visits evaluation. The results following the implementation of GMP initiatives, indicate improvements in operational efficiencies through training of qualified personnel for proper hygienic and quality practices, cleanup of total premise and storage space reorganization, improved ventilation, contamination control, and minimize wastage, development of 26 SOPs for manufacturing processes and procedures, prevention and detection of product contamination, pest control inspections and records, development of raw material codes, improved materials management, development of preventive maintenance schedules, and stakeholders commitment to the project. Their commitment will determine the ability of the company to attain GMP certification and business survival.

Keywords: Good manufacturing practices; Quality standards; Personnel hygiene; Maintenance; Contamination control.

JEL Classification Codes: L6; L65; L52.

1. Introduction
Good manufacturing practices (GMP) can be considered as a regulated policies, codes or even guidelines that govern the operations of cosmetic, drugs, food, and medical devices manufacturers. It is basically a combination of manufacturing and quality control procedures aimed at ensuring that products are consistently manufactured to their specifications. In Malaysia, the production and sales of cosmetic and drug products is governed by the Control of Drug and Cosmetics Regulation 1984, and this regulation is enforced by the National Pharmaceutical Control Bureau (NPCB)\(^1\). Hence, all cosmetic and drug products have to undergo quality control inspection by NPCB. NPCB ensures quality, efficacy and safety in cosmetics and drugs through the registration and licensing scheme. This body also monitors the quality of registered products into the market and any adverse drug reactions. The Control of Drugs and Cosmetic Regulations require that all cosmetics and drugs sold in Malaysia must be registered with the Drug Control Authority, and the manufacturers, importers, and wholesalers must be licensed. The manufacturer must disclose all the composition or ingredients of any cosmetic or drug products before it can be registered. These products must be manufactured, packed and stored under sanitary conditions as stipulated under the GMP requirements. The main purpose of GMP enforcement is to ensure products are of high quality and safe from contamination. Beginning 1\(^{st}\) February 2002, all manufacturers and importers of cosmetics and drug products are required to submit their products for registration to the NPCB. A transition period of 2 years (until 31 December 2003) is given to industries to register their products. Within this period, the industries can continue to market

\(^{1}\) The National Pharmaceutical Control Bureau (NPCB), formerly known as the National Pharmaceutical Control Laboratory, was set up in October 1978 under the quality control activity of Pharmacy and Supply Programme. This institution was established to implement quality control on pharmaceutical products.

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their products while waiting for products approval. Therefore, by 1st January 2004, all cosmetic and drug products must: be registered, packaged, and labeled in accordance to the requirements; be manufactured and stored at a licensed site according to GMP and good storage practices; and have their adverse reactions reported to NPCB in accordance to the requirements. These companies were then given another two years to prepare their companies in accordance to the GMP requirement. Failure to fulfill this requirement by January 2006 will result in inability to obtain manufacturing license from NPCB. In order to enhance the GMP practices in Malaysia, current study examines and analyzes company X (fictitious name), located in Kedah, Malaysia, that produces body, skin and hair care products, as well as, cosmetic and food supplement products. The objective of this paper is to analyze whether the current manufacturing practices of company X comply with the standard requirement of GMP. At the end of this paper, the managerial implication was discussed to improve the manufacturing practices.

2. Good manufacturing practices

GMP is defined by World Health Organization (WHO) as “that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization”. The key element of GMP includes: a) qualified and trained personnel; b) adequate premises and space; c) suitable equipment and services; d) correct materials, containers and labels; e) approved procedures and instructions; f) suitable storage and space. The guiding principle of GMP is that quality is built into a product, and not just tested into a finished product. Therefore, the assurance is that the product not only meets the final specifications, but that it has been made by the same procedures under the same conditions each and every time it is made.

3. Case study: A cosmetic and food supplement producer

Company X manufactures goat’s milk based cosmetic and food supplement products for its parent company. It is to be sold in the Malaysian markets and several ASEAN countries. Starting with only one product i.e. goat’s milk soap in 1999, company X has now expanded its production operations to include production of body care, skin care, hair care, cosmetic products and food supplement. Among the products manufactured are goat’s milk based bar soaps, body scrubs, body lotion, skin cleanser, skin freshener, skin moisturizer, hair shampoo and moisturizer, lipstick, lip gloss, and flavored goat’s milk food supplement tablets. To date the company is producing more than 30 product items in its factory.

The company highly believes that in order to sustain its longevity and ability to compete with others, its products must be of high quality and able to satisfy consumer needs and wants. Due to that, company X research and development (R&D) department has been assigned the responsibility to progressively develop quality products and to conduct product testing from time to time. In line with its parent company’s vision “to become the leader in goat’s milk and biotechnology based products”. Company X mission is “to become a lead producer of high quality goat’s milk based products using highly sophisticated technological equipment”.

Currently, company X is supported by nine (9) permanent and two (2) contract employees. These employees are mainly machine operators, except for the Production Manager (PM), Product Development Executive (PDE), lab assistant, general clerk, and the storekeeper. Their personal files contain individual biodata and letter of offer that seems to indicate that all the employees have the required qualification and experience to hold their current position. There is no record of current job responsibilities, training received, performance evaluation and achievements, as well as rewards received. The type of training provided is on-the-job training from either their predecessor or their current co-workers. Some machine operators have been working with this company since its inception, and they received training on machine operations from the machine supplier. Once in a while, PDE will be sent to attend seminars or conferences on product development. The machine operators will occasionally be informed of any new development in their area of expertise.

These employees are assigned to three different functional areas (departments), namely: production, research and development (R&D), and administration. The production department is responsible for maintaining the production machines, developing the production plan, and producing products.

2 Guidelines for manufacturers have been established in August 2008 entitled Drug Registration Guidance Document (updated September 5, 2008).
Meanwhile, the administration department is responsible for inventory and storage management, suppliers’ delivery, disseminate raw materials to production and distribution of finished goods to marketing division. Lastly, the research and development department is responsible for research and development of new and/or improved products, as well as conduct product testing to ensure level of required quality is attained.

To date, there are three fully-automated machines that are used for producing company X products, which are: (i) soap production machine, (ii) cosmetics production machine, and (iii) tablet production machine. Two to three employees are employed to man each machine. Since the machines are fully automated, company X usually does not have any problem in meeting the demand for any of its products.

4. Method
The initial meeting between the researchers and company X begins with a diagnosis, understanding the business operations and identifying areas for further investigation. It is also important to understand company X’s needs and whether the purpose of research is in line with their needs. Since the client is interested in their current practices compliance and/or noncompliance to the GMP standards, the researchers believed that an “Adequacy Audit” on the company main operations and functions is necessary. The information gathered from the adequacy audit will provide insights on the level of compliance to the GMP standards. Following which corrective action can be suggested and proper action can be administered by the company. For these reasons, interviews were conducted, observation and collection of secondary data is carried out.

For the purpose of the audit, a comprehensive checklist was developed based on Control of Drugs and Cosmetics Regulations (1984) by Drug Control Authority, Ministry of Health Malaysia; Good Manufacturing Practices Guidelines (2002), by Health Products and Food Branch Inspectorate, Canada; and Malaysian Standard MS1514:2001 General Principles of Food Hygiene, by Department of Standards Malaysia (2001).

It took three full working days for the researchers to complete the extensive adequacy audit. For this purpose the researchers audited the laboratory activities, incoming inspection processes, warehouse management, mini-storage room at production floor, production processes, packaging processes, and administration office. The researchers reviewed the preventive maintenance documents and files; and interviewed some of the personnel. The discussion revolves around six main issues: a) qualified and trained personnel; b) adequate premises and space; c) suitable equipment and services; d) correct materials, containers and labels; e) approved procedures and instructions; f) suitable storage and space.

5. Results and discussion
The researchers found that several issues on personnel hygiene, inadequate premise cleanup and maintenance, poor equipment preventive maintenance, poor materials handling, labeling and contamination control, lack of procedures and instructions, insufficient process controls and storage space management. The analysis of the findings was discussed below:

Qualified and Trained Personnel
The Analysis.

The audit revealed that the employees of company X are competent and capable of carrying out their tasks efficiently. This is due to their ability to operate and maintain the machines and extensive knowledge about production process and raw material consumption in generating every product. However, their level of awareness on GMP is relatively low. Their knowledge on “quality” and “hygienic practices” are rather limited. Only one executive has been trained for formal GMP application. Hence, one of the most important aspects that require the company immediate attention is employees’ knowledge on GMP and readiness to GMP initiatives.

Secondly, employees’ personal files are found to be poorly maintained. GMP requires extensive documentation of the training received by the employees and record of historical performance evaluation as well as their expected future performance. In addition, job description for each job should also be made accessible for employee reference. As a result of not having all these records, there is lack of monitoring of employee performance, lack of training needs and employee development programs.
Solutions Suggested.
Due to the problems listed above, a training program on GMP is greatly needed to create awareness and to provide new knowledge to the employees. Taking into consideration their academic qualifications, the researchers believed that the training should focus on basic GMP practices for employees’ easy understanding and application in their daily operations. Besides training on GMP awareness, practical training on hygienic practices in accordance to GMP requirements should be considered. It is also important for employees to understand the reasons for practicing good sanitation and health habits at their work place. Enhancement of skills and knowledge will enable them to perform and deliver their tasks efficiently and effectively in accordance with GMP standards. Thus, reducing the risk of contamination of products is a necessity. Furthermore, the company needs to establish written procedures that define the standard requirements for the sanitation practices for future reference. The responsibility to ensure compliance to the sanitary practices should be taken by the production manager.

Executives and supervisors are also advised to regularly update their subordinates’ personal file. All training, including on-the-job training, must be documented. Individual performance must be assessed periodically (annually or biannually). Recognition of individual’s good performance and team efforts should be initiated so that outstanding individuals or team can be rewarded accordingly. One of the GMP main concerns about personnel is having qualified individuals for the right job at the right time. Failure to document employees training and performance evaluation and achievement indicate lack of evidence in fulfilling the GMP requirement.

In addition, getting people to be committed to GMP initiatives can be rather difficult. Resistance to change, additional work load, new procedures, new techniques, less time for relaxation, reduce outputs using new methods that results in significant reduction of income for the operators. As such, it is recommended that this company review its compensation scheme to encourage participation in generating more outputs and reduce resistance to change.

Actions Taken.
Firstly, a training needs analysis was performed. The information gathered provide the researchers with specific areas that require immediate attention of training needs. This include introduction to GMP, good practices according to GMP, and good storage management. A one-day training program entitled “Kursus Pengenalan Kepada Amalan Pengilangan Baik” is tailored specifically to fulfill the needs of Company X employees. Special attention is given to employees understanding, participation and application. The training covers the basic aspects of GMP that include the importance of quality and GMP, GMP practices and good storage management practices.

To significantly improve hygienic practices, employees are trained on the importance and methods of maintaining personal cleanliness prior to commencement of work. Practical methods and reasoning about wearing outer garments, rubber gloves, masks, caps, beard covers, and hairnets were thought while performing their production work. Previously these employees did not fully observe the need to wear these protective garments due to lack of understanding and the reason for wearing them. After the training session, drastic changes took place as these employees have fully observed the dress code requirements before starting any production work.

Nevertheless, the cleaning and sanitizing process in accordance with GMP standards was not shown to the employees due to insufficient time. No practical training was provided to them. Therefore, practical training on hygienic practices needs to be conducted sometime in the future.

The effectiveness of the one day training can be seen immediately. Firstly, the training evaluation feedback indicates a positive reaction from the employees to the training program. They perceive that the training provide very useful insights on GMP application and improved their daily tasks performance. Secondly, gaining more knowledge on GMP application makes it easier for employees to communicate and discuss GMP related matters. Sharing information pertaining to their work is evident with less worry about their job security. Thirdly, drastic changes in the behavior pattern are observed as the employees take the initiative to apply good manufacturing practices. For instance, the employees themselves are more diligent and concern about wearing protective clothing such as caps, hairnets, garments and gloves. Simple sanitizing process is carried out at their own initiatives.
Adequate premises and space

The Analysis

It is obvious that the current building, formally designed to operate a first class restaurant, is not meant to be a factory for cosmetic industry. The location itself is not suitable. According to the managing director, this company does not emit any harmful gas or substance into the surrounding area. As such, it is safe to operate. On the other hand, a lot of logistics problem arise. The company is not able to build proper parking lots, access roads leading to store. As a result, loading and unloading of materials into and from trucks becomes a problem.

Furthermore, the layout of the building makes it difficult to run an efficient production operation due to the original layout was meant for a restaurant. The production rooms are too small and poorly ventilated. The lab does not have a ventilation system. The packaging area does not have any protection from contamination. The storage rooms are scattered everywhere throughout the building. In addition, the production floor provides a pathway for access to offices located at the back of the building. All these are possible sources for contamination. Fortunately, the company does provide adequate hand washing facilities, which is important for sanitation purposes before and during the production activities. Thus, contamination from material handling is minimized.

Solutions Suggested.

To have a GMP status, a factory does not have to be big. In fact, the GMP requires that a plant building and structure should be of a size and design to facilitate maintenance, cleaning, and sanitary operation, and to prevent mix-ups between raw material and products. Renovations may be necessary meet this requirement. However, since current premise is too small a size, renovating it would be a waste of money. Therefore, the only solution is to relocate the factory to a new site and necessary steps have been taken to relocate the building.

However, relocation cannot take place immediately. An alternative solution is to clean up the plant and the surrounding area, getting rid of all potential contaminants. In addition, minor renovations like installing air condition in the production areas and laboratory would reduce contaminants. Alternative route to the offices located at the back of the building is unavoidable. It is also important for the plant to have good ventilation, air filtration, heating and/or cooling system to control micro-organisms, dust, humidity and temperature. This is to prevent contamination of products and to provide a safe and clean working environment.

A poor ventilation or air filtration system could be dangerous to the health of the employees. Due to lack of exhaust fan, the employees at the lab prefer to open the windows to release unwanted odor and fumes that result from their experiments. The production employees also leave the shutters open during production. This is a bad practice because experiments and products are exposed to air borne particles and other contaminants. Therefore it is also suggested that the lab windows and the production room shutters should be kept close all the time.

To prevent product contamination, the researchers suggest that the production area should be restricted to authorized personnel only. Allowing unauthorized personnel into the production area is another source for contamination. Proper sanitizing procedure should be imposed and protective garments should be provided for personnel that need to pass through production floor. The researchers suggest that signs be placed at the entrance of each production room to prevent unauthorized entrance. In addition, signs about potential danger, safety practices and conduct, as well as hygienic practices are also recommended.

Besides that to comply with GMP requirements, the plant should provide adequate facilities for the well being of the employees, such as toilet facilities, eating room and locker room. At the moment there is no eating room or locker room available for the employees to use due to lack of space. However, the researchers do indicate that the company should take this into consideration when they build their new plant.

Actions Taken.

The owner of this company is aware of the inadequacy of this building, and he is currently in the process of relocating the plant elsewhere. However, this cannot be achieved within the next few months. Therefore, at the moment the company intends to adopt the good manufacturing practices as
much as possible so that the GMP practices continue to be applied when they move to the new site and be efficient, effective and productive as soon as possible.

As suggested by the researchers, the company conducted a company-wide cleaning operation in late December. The employees cleaned up the storage rooms, rearrange the packaging materials in the store for easy access. In addition, they also cleaned up the termite nests and exterminate the affected areas. Also, the packaging materials stacked on metal pellets are arranged two feet away from the wall to prevent future termite attack. The floor is injected with anti-termite chemicals.

The packaging area is covered with big nettings from ceiling to floor to prevent bats from entering the area. Previously the area was contaminated with bat droppings causing contamination and losses to the company.

With regard to unauthorized personnel entering the production floor, the Production Manager accepts the suggestions by the researchers to ensure no trespassers in the area. Employees not involved in the production process are prohibited from entering the production floor without authorization from the Production Manager. In fact, signs which indicate this were also mounted on the doors that lead to the production floor.

Other types of signs that remind people about potential danger, safe conduct, and hygienic practices are also mounted on the walls in the production area. Access pathways into marketing offices located at the back of the building is made available via entry from a gate at the left side of the building.

Suitable Equipment and Services
The Analysis.

Company X uses fully automated machines which are design and built to prevent contamination. The company also makes sure that all other utensils and equipments does not become a potential source of contamination. Most importantly, all machines and equipments are properly kept and handled. Cleaning of machines is carried out immediately after each batch production. Hence this makes the company machines and equipments ready to be used for the next batch production operation. All these are good manufacturing practices. Unfortunately, major machine maintenance service has never been conducted and this could be detrimental to the lifetime of the machine. Not only machine maintenance is neglected, building maintenance is also not done periodically. Though the company knew that pests could contribute to contamination, there is no initiative on the part of the management to conduct pests’ control and pests’ treatment periodically. Hence, termite’s nests were found at several areas within the building (i.e. at two of its packaging materials rooms and on one wall of its tablet production room). Furthermore, since the company has planned to move to a new plant in the near future, there is a possibility that the company management also hesitates to invest on costly pests’ treatment. Such decision could only make things worst and delay the process of complying with GMP standard.

Solutions Suggested.
The company should understand preventive maintenance is not only to ensure that the machines are operable during production. It is also to lengthen the lifetime of the machines itself. Therefore, the researchers suggested that the company should perform periodic maintenance check and services to ensure the machines are always in a tip-top condition and can be used for many years to come. Moreover, it is also important that the company keep record on every maintenance services, and to include information on newly installed parts. This is to facilitate future maintenance arrangement. It is also advisable that all cleaning agents and equipment be kept in a separate area so that mix-ups and recontamination can be prevented.

Knowingly, management should conduct pests’ treatment periodically to cleanup termite nests, and pests around the building. This is because the company is producing body care, skin care, hair care and cosmetics products. Having pests in the production area can cause severe contamination problems. Hence, pest extermination should be conducted periodically (monthly basis). In addition, they should be careful with the use of insecticides and pesticides, and should protect against the contamination of raw materials, products, equipments or packaging material. Lastly, the company should also maintain written records of pest control inspections. This is important so that they know when the next inspection is due and when to schedule the next extermination.
Actions Taken.
The Production Manager has agreed to all suggestions put forth by the researchers regarding machine maintenance, and the separation of cleaning agents and equipments to prevent from cross contamination. However not all suggestions have been implemented. To date, the action taken is only to prevent pests from contaminating the production and packaging areas. In order to prevent bats from going into the packaging area and contaminate it with bats droppings, a big net was fixed from the ceiling to the floor around the packaging area. As for the termite problem, termite’s treatment has also been conducted. Other than that, efforts to conduct machines maintenance service and to produce written records of maintenance and pest control have not materialized.

Correct Materials, Containers and Labels
The Analysis.
GMP guideline basically points out the means to prevent product contamination and mix-ups so that quality can be assured. Compliance with GMP requires the correct materials are being used in the production processes, the appropriate containers are being used to store raw materials and end products, and accurate labeling are placed on all containers. To ensure correct materials are used in the production process, the current practice of the company involves a visual check of the materials by the operator. The labels that are available on the containers become a major reference to the employees, besides the condition of the raw materials. However, the operator does not have anything that he can use to verify his judgment regarding the condition of the materials. All is based on their experience. However, since the raw materials are kept at a temperature that protects it from deterioration, there is little worry that the quality of the products is forsaken.

With regard to the containers, all raw materials are stored using the containers provided by the suppliers; hence it is not a major issue because preserving those raw materials is the concern of the suppliers. However, company X is responsible to ensure the packaging materials, which are also the container of the end product, will protect them from contamination. Since the company claimed that they have never had problems with bacterial count or any complaints from customers, it indicates that the packaging materials are suitable for the product that they contain. Nevertheless, product quality tests, duration tests, should be conducted periodically to ascertain that quality is maintained, and certification from NPCB is obtained. However, since product labeling is done manually, the company must be careful that the correct labels are paste on the products. Since the labels that contain information on batch number and manufacturing date, expiry period and MAL code are printed by the company itself, it can be made whenever it is needed.

Looking at the organizational chart, it seems that currently the company has no quality control unit to perform quality assurance. In most organizations this department monitors the activities of the production department and the quality of the end products. Yet, this does not mean that aspects of quality assurance are being neglected in company X. This is because the Product Development Executive is assigned to look into this matter. However, her responsibilities are restricted only to product batch samples testing of cosmetic products. What about the quality of the body care, skin care, hair care and tablets products?

Solutions Suggested.
Company X’s aim is to become a lead producer of high quality goat’s milk based products. This objective will only turn into a reality if “quality practices” is applied in all aspects of the company production activities including materials handling, processing, packaging, labeling and storage. Furthermore, in order to ensure quality products for customer satisfaction, GMP procedures must be strictly followed. Due to that a “quality control unit” should be established so that quality control operations can be employed to assure the company products, its production processes and the materials used in the production conform to GMP standards of purity, quality and composition, and that packaging materials are safe for their intended purpose.

Company X current quality procedure is considered as insufficient to guarantee that products are totally safe and free from defect. Hence procedures, specifications and test methods to approve or reject all raw materials, work in process, finish products quality control, packaging materials, and labeling based on GMP conformance need to be established. Every inspection and tests performed on raw materials, work in process, finished goods, packaging materials must be recorded, analyzed, monitored and filed for future reference, in the event if any consumer disputes should arise.
Also, it is a concern for company X to continue using raw materials in production process using original containers and labeling purchased from suppliers. This lead to operators being able to identify types of raw materials used, risk of product formula is known to operators, risks of trade secret processes being leaked to competitors, and risks of theft of valuable raw materials. As such, using of original labeling from suppliers should be replaced with product codes designed by company X. For this reason, it is recommended for company X to develop a set of codes identifying the raw materials for use in production. This will protect the above risks.

**Actions Taken.**

Even though, a quality control unit is crucial at this point, company X is unable to set up the unit due to budget constrains. However, the quality control unit is expected to operate upon moving to the new building in the near future. Until then, the current practice still applies. In addition, the company is still unable to establish a method/procedure to ascertain the quality of body care, skin care, hair care, cosmetics and food supplement tablets, or to verify judgment made by the employees regarding the visual inspection on the usability of raw materials.

Nevertheless, the company agreed that using the original label is risky. Thus, company X has developed raw material codes and re-labeled the raw material containers using such codes. Furthermore, by using code labels it would be easier for employees to recognize and pick-up the right materials by looking at the codes. According to the Production Manager, the Product Development Executive has assigned codes to each raw material, and efforts have been made to print and to stick the new coded labels on all raw material containers purchased.

**Approved Procedures and Instructions**

**The Analysis.**

As claimed by the Production Manager, company X employees are provided with on-the-job training. During the training session, employees are usually briefed on how to handle critical processes including machines and raw materials. However, the instructions and procedures explained to them have yet to be documented or recorded. These practices do not conform to the standard set for GMP. According to the GMP standards, instructions and procedures involving all critical processes must be written in clear and unambiguous language so that employees can easily read and understand its contents. Since, the employees have to depend on their memory and previous experiences in completing their job, it is obvious that this company has not develop any operating procedures that the employees can use as a reference.

**Solutions Suggested.**

In compliance with GMP, management is accountable to develop a Quality Manual. This manual basically, provides the overall guidelines and company policies toward implementing GMP. On top of that, written procedures for production operations, process controls, quality controls and laboratory operations should be established and up-dated. Without these documents it would be difficult for the company and its staff to provide evidence to NPCB that the company critical processes are being performed according to its specifications. Given that, the executive has too many responsibilities on hand and attention on this matter is critically needed. It is suggested that management assign qualified staffs to assist in preparing the required records and documents. In fact, qualified and experienced operators should be encouraged to provide inputs in developing the procedures and format for maintaining a record. Employees’ participation in development of process procedures, documentation and records will result in higher commitment during implementation process.

**Actions Taken.**

With the help of the researchers, all necessary standard operating procedures (SOPs) for company X critical processes were identified. A small workshop was then conducted by the researchers to help and facilitate the company in designing and documenting its SOPs. The people who are involved in this workshop include the Production Manager, the Product Development Executive and the general clerk. The result of the workshop was surprising. Within two weeks time, the three member team was able to develop 26 of 32 complete SOPs. Meanwhile, the executive has yet to finish writing up the company’s quality manual.
Suitable Storage and Space
The Analysis
The findings revealed that the management of company X does not prioritize the proper method of application for storing and handling raw materials, work-in-process products, packaging materials and also finished goods as a means of prevention from contamination. This is evident from the condition of its storage rooms. It is a good practice to have separate rooms for storing packaging materials, raw materials and finished goods. However, the problem is that the rooms are not properly organized. If the employees have difficulties in reaching for the materials located at the back of the room, then it to various other storage issues including space management, safety of materials from contamination, damage products, expiry, uncontrolled pests attack, difficulty in searching for materials, and lost of time and costs.

Nonetheless, in the raw materials storage room all materials are kept in containers and under appropriate conditions of temperature. This would prevent the raw materials from deterioration and contamination. However, proper identifications are given to some containers of raw materials and finished goods to prevent product mix-ups. At the same time, product arrangements are poorly organized without any basis of good storage practice. Lastly, even though company X claimed that they use the FIFO method in the consumption of raw materials, the current store room arrangement hinders this method from being conducted efficiently.

Solutions Suggested.
The researchers believed that improvements on handling and storage of raw materials, in-process materials, packaging materials, and finished goods are highly needed. This means the company needs to reorganize the arrangement of its raw materials, packaging materials and finished goods so that the systematic FIFO method can be applied efficiently and effectively. Furthermore, it is suggested that the packaging materials are stored according to the types and sizes of material. For example, all carton boxes should be kept in one room while the bottles and tubes are kept in a different non-contaminated room. This arrangement is more congruent to GMP standard and it simplifies the search process. In the case of raw materials it is suggested that the company segregates raw materials according to types, and sizes, placing the frequent usage materials at racks that can be easily located. Location of materials should be labeled and traceability in the system is evident.

Written procedures for types and method of storage and handling of raw materials, packaging materials and finished goods must be established. Only then it would be easier for the management to strictly implement the procedures effectively and reduce material damage and minimize losses. The employees would also know what is expected from them.

The Actions.
Several changes have been made in the company store rooms. In the packaging materials store room, all carton boxes are stored by types and sizes with identification labels, and arranged on pallets in the middle of the room leaving at least two feet of space between the materials and the wall. The floors are injected with anti-termite chemical and the corners are sprayed with pest control powder. This is to eradicate termite and other pests attack and also to allow the store keeper to have access to materials from all corners.

The raw materials store room has been re-arranged and reorganized for easy access and searching for the raw materials. Since the room is small and racks are inappropriate, the floor is labeled with red line and yellow line boxes, segregating the material containers by types and sizes. The containers arrangement allows for a small pathway between containers for easy access. The use of rope as a method of segregating the materials is removed from the room. Most importantly, this new arrangement created sufficient space for employee to move materials in and out from the store room.

The finished goods room has also been re-arranged by product type and sizes with complete identification labels. The finished product packed in carton boxes are kept at room temperature and arranged base on fast and slow moving products. The key is for easy access to the products needed, and the quantity are easily monitored.

6. Conclusion
The GMP adequacy audit reveals that the root cause of non-compliances can be attributed to four main factors, namely, lack of knowledge on GMP practices on the part of its staffs, lack of urgency and
supervision on the part of management, lack of priorities in material handling and lack of financial support to prepare for GMP certification. Since implementing the GMP initiatives, improvements in operational efficiencies is achieved through training of qualified personnel for proper hygienic and quality practices according to GMP standards. Adequate premise and space management lead to cleanup of total premise and storage space reorganization for easy access, improved ventilation, contamination control, and minimize wastage. Suitable equipment and improved services initiatives results in prevention of contamination, and pests preventive controls. Preventive maintenance is planned and yet to be materialized. Correct materials, containers and labeling allows for usage of codes for raw materials and containers and proper labeling. Approved procedures and instructions lead to development of 26 SOPs in areas of purchasing lab equipments, receiving samples, determining codes, labeling, cosmetic products quality control, producing cosmetic products, food supplement tablets, body and hair care, developing new products, rejecting defective products, applying smart cards for registering new products, registering with NPCB, halal certification, procedures for purchasing, receiving materials, producing, packaging, batch numbering, and issuing materials from store. Suitable storage initiatives results in total cleanup storage rooms, as well as reorganization of storage space and materials management.

Indeed, there are still many more that the company should do in order to see a more substantial change in terms of performance and preparation for GMP certification. More resources are needed in order to ensure GMP certification process is swift and successful. Financial support on new building is required and training for advance GMP practices are needed. Subsequently, training programs for Hazard Analysis and Critical Control Point (HACCP) certification needs to be planned in the organization strategic plan.

This case indicates that small and medium size industry can obtain GMP certification with initiatives planned according to GMP standards. Once the company is GMP certified, it can produce much more products targeted for export market. There are bound to be many other small industries that would want to engage in contract manufacturing. Furthermore, GMP certification will also increase consumers' confidence in company X products which would result in higher sales and with proper cost controls, would lead to higher profitability. Until then, company X must continue with its effort to further comply with other aspects of GMP requirements because it will only lead to better financial performance for the company.

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