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The Implementation of Good Manufacturing Practice in Polycarbonate Film Industry

Nisachon Mawai, and Jeerapat Ngaoprasertwong

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***Abstract*—**This study reports the implementation of Good Manufacturing Practice (GMP) in a polycarbonate film processing plant. The implementation of GMP took place with the creation of a multidisciplinary team. It was carried out in four steps: conduct gap assessment, create gap closure plan, close gaps, and follow up the GMP implementation. The basis for the gap assessment is the guideline for GMP for plastic materials and articles intended for Food Contact Material (FCM), which was edited by Plastic Europe. The effective results of the GMP implementation in this study showed 100% completion of gap assessment. The key success factors for implementing GMP in production process are the commitment, intention and support of top management.

***Keywords*—**Implementation, Good Manufacturing Practice, Polycarbonate Film, Food Contact Materials.

I. Introduction

THE polycarbonate film manufacturing unit was one of business units of the company in this case study. The company had a diversified product portfolio, including the polycarbonate film manufacturing unit. The main use of produced film was for food contact and medical applications. The film production was under control by the excellent management system in order to ensure that the production was complied with the GMP regulation. Safety and health of consumers were the first concern of the company. Consequently, the company also set the policy for the relevant production plants in polycarbonate business concerning GMP. The policy also included the direction for communicating and for giving information to contractors, who concerned to the activities or production process that had to be complied with GMP.

In order to fulfill the requirement of trading partners in European Union (EU), EU regulation requires that compliance of FCM of the Framework regulation 1935/2004 must be achieved through good manufacturing practice (GMP): migrations must not endanger human health, bring about an unacceptable change in the composition and deterioration in the organoleptic characteristics of the food. The recent GMP Regulation 2023/2006 [3] defines GMP as assurance of quality in term of conformity with the rules at all production states and for all types of FCMs.

GMP basically ensures the prevention of cross contamination and the full control of potential impurities. Under GMP regulations, manufacturers have to make certain that all production processes are fully complied. This involves quality assurance of raw materials, manufacturing, procedures, premises and equipment, and training of employees. A quality control system must be in place and the documentation of production operation and quality control must be kept. This accountability extends throughout the supply chain with manufacturers needing to prove they have obtained raw materials from partners that are also GMP competent. [5]

The implementation of the manufacturing plant is a continuous process, considering PDCA cycle (Plan, Do, Check, and Action). It can be divided in four steps: conduct gap assessment, create gap closure plan, perform gaps closure and re-evaluation of corrective measures implemented [4]. The created gap assessment step and re-evaluation of corrective measures implemented steps are usually carried out by auditing the processing facilities using the guidelines for GMP for plastic materials and articles intended for FCM, which was edited by Plastic Europe [6]. The gap closure plan was generated after auditing, while the gap closure require to improve the working and production processes in the polycarbonate film manufacturing plant in order to be in line with the requirement of GMP. In this study, the risk assessment, using FMEA (Failure Mode and Effect Analysis) was used to address the cause, opportunity, severity and analyze the root cause. Then, the cause could be eliminated and problem could be prevented [1].

In additional, the questionnaire of problems and difficulties for the GMP implementation of the other food contact material industries, which also produced food contact product and already achieved in GMP implementation was performed by finding the opinion, collecting problems and difficulties in implementing GMP, and summarizing the common facts.

The objective of this study is to show that the manufacturing plant could implement GMP system in its operation. This implementation can create more value from the acceptance in food contact material industry. The contribution of this study is to be the best practice for the other food contact material industries. Then, the fast ways for other manufacturing plants to implement GMP are expected.

Nisachon Mawai, Department of Industrial Engineering, Faculty of Engineering, Chulalongkorn University, Bangkok, Thailand, (nisachon.m@chula.ac.th)

Jeerapat Ngaoprasertwong, Department of Industrial Engineering, Faculty of Engineering, Chulalongkorn University, Bangkok, Thailand, (jeerapat.n@chula.ac.th)

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II. Material and Methods

A. Characteristics of the Polycarbonate Film Processing Plant

The manufacturing unit was located in eastern region of Thailand. The plant used 100% of Polycarbonate resin to extrude thin films from it with an annual A-grade output capacity of 250 tons per month. The polycarbonate resin was conveyed either from the silo or from 1.5 ton of big bags to the extruder. A melt pump drives the melt through a wide die, which produces the film. This film was caught between embossing rolls, to define the final surface. In a few consecutive steps, the film was trimmed to its final width, a protective masking film is applied and rolls of film are produced. These rolls were the final product in most of the cases. Sometimes, the rolls were cut into sheets on one of the 2 cutting machines. Finally, the products were packed and prepared for transportation. All steps mentioned operations took place in a clean room environment.

B. Implementation of GMP in the Polycarbonate Film Processing Plant

The implementation of GMP in this manufacturing plant was started by top management, who created GMP policy and regular. According to Commission Regulation 2023/2006 for material and articles intended to come into contact with food, besides a quality management system and appropriate documentation, the regular requires to the implementation of an effective quality assurance system with GMP forming an essential part thereof. The implementation of GMP requires gap assessment, the development of gap closure plan and final execution of the plant.

A multidisciplinary team composed by plant manager, QES manager and all concern managers was formed. The implementation of GMP was carried in four steps [4] as follows:

1) Gap Assessment

This step aimed to provide information on the current hygienic and manufacturing practice adopted in the manufacturing plant before implementation of GMP [4].The gap assessment (internal audit) was conducted by a global GMP specialist team according GMP Regulation 2023/2006 and guideline for GMP for plastic materials and articles intended for FCM. The guidelines contains 9 sections, in total 44 items: 1) quality assurance system and quality policy, 2) management leadership and personnel, 3) hygiene policy, 4) documentation, labeling, document retention and traceability, 5) production: 5.1)starting and/or raw material specification and acceptance, 5.2)contamination prevention, 5.3) management of change, 5.4) storage, packing, warehousing and transportation, 6) Quality control and specification 7) work contract out, 8) Complaint handling, product recall, and incident management, and 9) regular internal and supplier audit

For each item of guideline assessed, a status of "conformity" when the requisite was fully adhered and "non-conformity" when the requisite was partially adhered or not adhered was assigned. Any further observations were also recorded at this step. The output of the gap assessment was report containing the results of the manufacturing plant status regarding the implementation of the GMP.

2) Gap Closure Plan

The gap assessment report was presented to the management team of the factory and discussed with the concern responsible and then, the management set up the multidisciplinary committee, which led by Quality assurance Manager. Managers of all concerned sections were assigned as committee members. They were trained in the GMP Training course in order to clearly understand the process according to the regulation. After that the plans for implementation, for control and monitoring and for evaluation were created and used. The plans had to be in line with the regulation of GMP No.2023/2006, which its content of 9 sections is set up by the Plastic Europe Association of Plastics Manufacturers. The time for implementing takes totally 6 months as below figure.

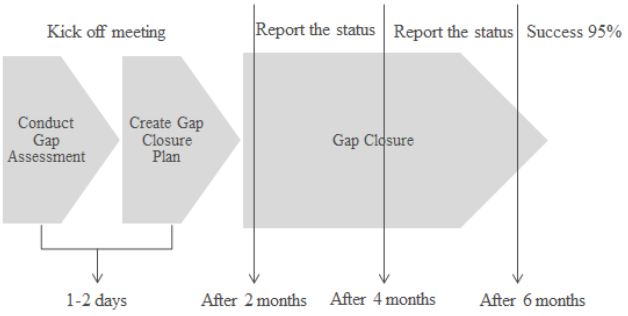


Fig. 1 GMP Implementation Schedule

3) Gap Closure

Gap closure is a state of implementation of corrective measure state in the gap assessment report.

In the first step, the management team provide training module to all employee. There are 3 training modules: module 1 GMP for management (Self learning), module 2 GMP for manager and supervisor level up, module 3 GMP for operator level. All the trainings were registered and all information such as name of employee, date and total time of training were recorded for future auditing.

The second is implementation step. The state of implementation of corrective measure state in the gap assessment report was done gradually base on immediate investments required as below.

Section1: Quality assurance system and quality policy

A general policy was existing without explicit "Food contract material" terms. The plant manager reviewed quality policy compliance assessment on EU regulation and announced in legal and others requirement database.

The manufacturing plant was certified according to ISO 9001, ISO 14001 and OHSAS 18001. Moreover, the procedures for Process Control, Lot release control, Quality inspection, Sales releases, Non-conforming materials, Raw material inspection were created and reviewed to fulfill an effective quality assurance system. A quality control department exists with responsibility and authority to independently approve/reject all materials in the process.

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Documented of job description of QC manager and organization chart

Section2: Management leadership and personnel

To cover the requirement in this section, management had to create the document showing the responsibility of all position in implementation of GMP by creating responsibility matrix including identified that the implementation of GMP in manufacturing process is the responsibility of all employees in all levels. All employees had to get training. The training matrix, training plan and frequency for each training had to be set.

Section 3: Hygiene policy

The manufacturing plant was fulfilled in this section. Critical processes take place in a certified clean room environment (some class 1,000, some class 10,000). The required hygiene measures to ensure these conditions and control them are in place. Housekeeping, cleaning and pest control programs are in place. The housekeeping and cleaning programs were based on the 5s principles and audited regularly.

Section 4: Documentation, labeling, document retention and traceability

The important documents for process control were documented, such as product formulation, operating procedures, operating windows, product release specifications and other critical information. Moreover, procedures to cover traceability from incoming starting material to outgoing specialty grades were also documented. Those procedures also took into account the use of raw material recovered from a production process, and the recording and traceability of their use. Most documents were stored electronically on servers, which were managed by a specialized site section, which was also ensured by back-up unit.

The extrusion lines of the plant had independent raw material feeding systems. They were built up in separated clean rooms. In any case, all grades were treated as specialty grades. Finished goods were discrete and have individual, clear labels – no mixing possible. However, according to the guideline for implementing GMP, the manufacturing unit had to set the labels that clearly identified including in the storage area for raw material and finished products, and even in database system. The area for storage raw materials and products had to be arranged for food contact product. The AVL (Approve Vendor List) had to be set according to the guideline of GMP. The GMP product for the manufacturing unit were produced only from 1 production line that all machines were identified the name and tag numbers. Consequently, there was no chance for contamination by using wrong machines. However, the production line was also used to produce the general products. Then, the working procedures were created for the process of cleaning before producing food contact products. In this working procedure, all sequences for cleaning the machines were written.

Section 5.1: Starting and/or raw material specification and acceptance

The manufacturing unit had own guideline for approval the suppliers of raw materials in order to ensure that the suppliers can supply materials according to the requirement concerning to quality, environment, and safety. The mentioned guideline also included the responsibility of each party and processes for approving the suppliers. All data was recorded in the Material Request Database. Moreover, the material that used for producing food contact products had to be approved by our system due to the suppliers that they were produced according to the GMP regulation. The relevant document had to be certified. All materials had to be listed and identified, whether they were according to the GMP regulation.

Risk assessment, FMEA (Failure Mode and Effect Analysis) technique, was analyzed to ensure that the starting materials was verified and accepted before used and stored or handle in manner which prevent their mix-up and/or adulteration. Moreover, to prevent the misused, non-conform of material was identified and controlled.

Section 5.2: Contamination prevention

FMEA was conducted to prevent contamination. Equipment and set up and all process were analyzed to preclude cross-contamination between materials for GMP grades and for non-GMP grades. The cleaning process for avoid cross contaminate was described in grade change procedure.

A physical separation system of the manufacturing plant was documented. The storage areas for raw materials and products were clearly managed. The labels of “GMP” were installed on the floor to avoid the wrong use of raw materials and finished goods.

Procedures for transferring, packaging or loading operations were also conducted FMEA analysis to avoid product contamination by sub-contractor.

Section 5.3: Management of change (MoC)

The management of change (MoC) of the studied company was closely controlled. Whenever, there was any change, which effected to health, environment, and safety, MoC of such issue had to be created. There were two control systems, which is based in Lotus note. The first one was MoC Database to ensure that all change by new product or by new product formula in studied company had to be recorded. The second one was Q-number system that was used to ensure that all change by new raw materials, new suppliers, or new measuring equipment had to be updated.

Section 5.4: Storage, packaging, warehousing, and transportation)

The manufacturing plant used the service by the service company for storage warehouse. The mentioned service company was responsible for transferring and storage raw materials and finished products. Before, the contract between the manufacturing plant and the service company did not cover the GMP regulation. Then, the plant manager reviewed the contract and added some content concerning to GMP into the contract in order to ensure that the service company can work in line with GMP regulation. Furthermore, the audit by sampling was conducted annually.

The manufacturing plant conducted the working procedure for the working process that concerned to GMP. Moreover, all employees had to be informed, in case the GMP product was producing. Then, the employees would work with more intent

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to avoid any contamination. For labeling the product, all employees had to be trained how to process and inspect the labels.

Section 6: Quality control and specification

The specification for starting and/or raw materials and finished products were kept in Material Request Database (MR Database), which specified the list of all raw materials concerning to GMP and not concerning to GMP. It also included the list of suppliers and specifications of raw materials and products. The quality assurance section and procurement sections took care for the list of suppliers and raw material specification, whereas the product specification was took care by Technical Product Management. Furthermore, starting and/or raw materials and finished products were monitored to verify their compliance and conformance with specifications by Eco-Audit, which was done by audit team of the manufacturing plant together without source to evaluate the compliance of the system weekly.

The manufacturing plant had only one type of food contact product. The specification of this product was identical with one that was used by other affiliated factories. The name of the product started with FA (Food Application) to show that GMP had to be applied.

The manufacturing plant also had the monthly inspection plan for all measuring equipment. However, they had to be re-certificated by approval institutes yearly. Besides, Process Control Technology (PCT) Division had the plan for maintaining them.

Section 7: Work contract out

The manufacturing plant used the service of the service company for storage warehouse. The mentioned service company was responsible for transferring and storing raw materials and finished products. Before, the contract between the manufacturing plant and the service company did not cover the GMP regulation. Then, the plant manager reviewed the contract and added some content concerning to GMP into the contract in order to ensure that the service company can work in line with GMP regulation. Furthermore, the audit by sampling was conducted annually.

Section 8: Complaint handling, product recall, and incident management

The manufacturing plant used GCMS (Global Complaints Management System), which was used globally, to handle the complaints of customers. This system consisted of data of customer requirements, data of products that were complained, investigation result, and result of root cause analysis. Corrective and preventive action for request of returned product was as a part of guideline, which was out of scope of the GMP regulation.

Section 9: Regular internal and supplier audit

The internal and external audits were conducted once a year and twice a year, respectively. The audits were conducted by integrated with audit of ISO 9001 system. For the audit of the suppliers, the manufacturing plant had the guideline for supplier audit, and mainly considers the result of annual supplier evaluation.

4) Re-evaluation and follow up

Monitoring of all items was depicted in the guideline used in the study. The working team was requested to monitor, ensure and motivate the employees to accomplish with the GMP implementation.

The yearly GMP audit was planned for the internal audit of the manufacturing plant, work-contractor and supplier to ensure the GMP standard was followed.

C. Failure Mode and Effect Analysis (FMEA)

Risk assessment was an analytical method, which was improved dramatically over the time; the 'zero risk' approach became unrealistic. Risk assessment procedures were required [2]. Applying an FMEA to the manufacturing plant can be divided in a series of successive steps. : analysis of the process in every single part, list of identified potential failures, evaluation of their frequency, severity and detection technique, evaluation of the problem and identification of the corrective actions and control plans that could eliminate or reduce the chance of the potential failures.

The manufacturer's risk can be assessed by calculating the so-called Risk Priority Number (RPN), which can be calculated by simply multiplying of severity of the potential failure, the probability of occurrence and the probability that the existing control and measures will fail [1]. The potential failure was identified during the production. The high score of RPN is mean high risk of failure. Then, it had to be corrected and improved to reduce the risk. The manufacturing plant used FMEA technique for analyzing to ensure that whole processes in the manufacturing plant were conformed to the GMP requirement. Table I. presents the part of risk analysis for the highest potential failure identified, action taken and RPN in each production process of the polycarbonate film.

TABLE I
IDENTIFICATION AND MONITORING OF IMPORTANT PROCESS PHASES IN (RANK AS RPN) IN THE POLYCARBONATE FILM PROCESS

Process	Failure Mode	RPN	Action Taken	Final RPN
Raw Material Transfer	Wrong material transfer	108	- Performance review - Auditional System supplier	90
Raw Material Receving	Wrong material receiving	162	- Implement WI for GMP warehouse. - Implement GMP Flag - GMP Overview Training/ Performance review,	90
Loading process	Wrong conveying material	256	- Provide RM Conveying Logsheet and Memo board - Implement GMP Flag - GMP Overview Training/ Performance review	96
Extrusion process	Improper extruder cleanning / improper set up condition.	108	- Provide cleaning check sheet - GMP Overview Training/ Performance review	72

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Process	Failure Mode	RPN	Action Taken	Final RPN
Cutting process	Wrong material cutting	105	-Implement GMP area and flag -GMP Overview Training/ Performance review	70
Packing process	Wrong packaging applied.	160	- Implement WI for GMP - GMP Overview Training/ Performance review	105
Finished Goods Storage and Handling	Storage of Finished Good Mixing between GMP and non-GMP Products	54	- No action	54
Finished good transfer	Wrong material transfer	108	- Performance review - Auditional System suppler	90

D.Questionnaire survey on the others food contact material manufacturing plant

The objective of this survey is to ask problems, difficulties for implementing GMP of others manufacturing plants, who also produced food contact product and already achieved in GMP implementation. The survey papers were sent to 4 types of manufacturing plants; polycarbonate plant, polycarbonate compound resin plant, thin film plant for food envelop, and food plastic packaging plant. Thirty sets of survey form were sent to each plant. In each survey form, it contained with 2 parts. The first part asked for general information of participants. The second part asked for the problems of implementing GMP in four aspects; personnel, resource, intention of management, and monitoring and maintain of GMP. Likert's scale is applied to measure all aspects concerned in the research, 1-5 for at all, not really, undecided, much and most.

In the analysis result, the percentage was used to explain the general information, whereas, the standard deviation (SD) was used to analyze and explain figure and each factors [7]. The hypothesis testing was also used in order to analyze whether four mentioned problems impact to the GMP implementation in the food contact materials manufacturing plant significantly. These hypothesis testing was run the result of analyses in SPSS program.

III. Results and Discussion

A total of 44 items were evaluated before and after the implementation of GMP according to the regulation GMP No.2023/2006. The initial diagnosis of the manufacturing plant for GMP implementation indicate the evaluation result, it was found that 39% was passing, 59%was not passing, and 2% was not concerned by the manufacturing plant, included the utilization of water in manufacturing process. Then, there was no consideration in this topic. In the section no. 5 Production, the percentage of not fulfills was highest at 34% then in the topic no. 6 Quality Control and Specification, and then the section no. 2 Management leadership and personnel not passing at 7%. After the manufacturing plant set up the multidisciplinary committee to work on training and gap closure as described in the implementation of GMP in the polycarbonate film processing plant step. After 6 months, re-evaluation was carried out and indicated the result that all gaps in all topics could be closed 100%.

The key success factors were the intention and continuous support of the top management, who was the leader for changing the organization in the GMP implementation. He also set up the responsibilities of each person, who concerned to GMP. The policy on quality was created, and management review was also conducted to check the productivity. Moreover, the top management also supported resources, which the manufacturing plant should have adequately, such as budget for maintaining the GMP system by document and information system.

For the problems, it was found that some employees and contractors did not realize the problem and did not believe in the benefit from GMP implementation. They did not comply with the regulation in working procedures concerning GMP. They did not get enough encouragement to clearly understand the importance of GMP implementation.

From the survey of participants, who worked in other plastic producers that also produced food contact materials by all 120sets of survey that were sent out, only 82sets were returned. The most participants were men at63.4%, most of them graduated with bachelor degree at 39%, most worked in production division at 61%, and most worked in their current companies more than 5years at 70.7%.For the most part, 29.3%of them had work experience for more than 24months. 15.9%of them, as the least part, had experience with GMP between 7-12 months. 67.1%of all participants were in operational level.

From the hypothesis testing, the result of t-test values at the significance level of0.05 showed that the four problems mentioned: personnel, resource, intention of management, and monitoring and maintain of GMP, impacted to the GMP implementation in food contact materials manufacturing plant significantly as result in Table II.

TABLE II
Hypothesis Test Result

Factors	Average score	SD	T-test	P-value
Personnel problem	3.86	0.86	4.752	0.000
The GMP monitoring and maintain problem	3.75	0.92	3.349	0.000
The lack of resources	3.71	0.80	3.371	0.000
The lack of intention from management	3.64	0.79	2.433	0.007

The survey result shown that personnel with insufficient knowledge, understanding, training and awareness on the GMP compliance are the first top problem. The second problem is the problem on monitor and maintain of GMP system. When, any error was found, there was no corrective

action. There was no review according to the plan. Moreover, there was no analysis or improvement according to the data from monitor. The third problem is the lack of resources, effective communication, documentation system, and suitable environment for working in the organization. The last problem is the lack of intention of top management to encourage employees on the benefit of GMP, to set responsibilities of employees and to set policy concerning to GMP.

The survey result showed the correspondence with the situation of the manufacturing plant. It can be said that the most critical problem was the personnel with insufficient knowledge, understanding, and awareness on the GMP compliance. Then, it is necessary to use effective monitoring system in order to force employees to work according to the GMP by focusing on participation of employees, implementation together with employees, two-way communication, discipline, training for enhance knowledge and understanding, and let employees know about the benefit of GMP both in abstract and concrete. The mentioned activities can sustain the GMP System. However, the cost and time of management process will be increased.

IV. Conclusion

The manufacturing plant could implement the GMP effectively. The key success factors were the intention and continuous support of top management including the sufficient resources for supporting and maintaining GMP system. The implementation of GMP could reduce non-conformities, increase quality of finished product, and create acceptance of the finished products for food contact material industry. The report of this study was shown to effectively contribute with the improvement in the quality base on the Framework regulation 1935/2004 and GMP Regulation 2023/2006. Moreover, this study was an example for other factories in food contact material industry that can be uses as a guideline for improving their process and their work in order to implement GMP effectively.

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