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Implementation of good distribution practice in a Thai pharmaceutical manufacturer

Pana Chinajitphan[1] and Oran Kittithreerapronchai[2]*

[1] Regional Centre for Manufacturing System Engineering, Faculty of Engineering, Chulalongkorn University, Bangkok 10330, Thailand
[2] Department of Industrial Engineering, Faculty of Engineering, Chulalongkorn University, Bangkok 10330, Thailand

***Corresponding author**:
Oran Kittithreerapronchai
oran.k@chula.ac.th

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ABSTRACT

Good distribution practice (GDP) has recently been adopted and practiced by the pharmaceutical industry in Thailand, complementing the supply chain perspective and fundamentally transforming the industry's quality landscape. This study proposed a GDP implementation methodology that integrates project management and quality risk management (QRM) to effectively identify, manage, and mitigate distribution risks. The project management framework provides valuable tools and approaches for prioritizing operational gaps, managing expectations, and securing necessary resources, while QRM focuses on the risk aspects such as operation impact, reputation, and cost for manufacturers. The methodology was successfully applied to a pharmaceutical manufacturer to ensure product quality during storage and distribution and to prevent counterfeit products from infiltrating the supply chain. This study provides 4 insights into GDP implementations: (1) fostering a project management culture, (2) utilizing existing templates and tools, (3) implementing continuous compliance monitoring, and (4) embracing digital transformation through information technology systems. This implementation represents an opportunity to engage executives and extend the quality program beyond manufacturing into logistic activities.

Keywords: good distribution practice; risk management; project management; pharmaceutical supply chain; Thai pharmaceutical manufacture; national regulatory authority

1. INTRODUCTION

Pharmaceutical products, encompassing both traditional and modern drugs or medicines, are essential for treating illnesses, preventing diseases, and safeguarding public health. Therefore, these products are regulated for their quality, safety, and efficacy. The consumption of poor-quality, harmful, or counterfeit pharmaceutical products can undermine public trust, potentially leading to illness, treatment failures, antibiotic resistance, and in severe case, fatalities. Hence, all stakeholder in the pharmaceutical supply chain (PSC), from chemical manufacturers to product distributors and consumers, as shown in Figure 1, must implement internal controls and external governance to ensure the safety and effectiveness of pharmaceutical products. Improper storage and distribution practice can compromise the quality and efficacy of pharmaceutical products (WHO, 2010, 2014, 2020).

In the Thai market, pharmaceutical products are primarily supplied by domestic manufacturers and international importers. Due to limited local capacity for manufacturing active pharmaceutical ingredients (APIs), most domestic manufacturers import raw materials for production. After manufacturing or importation, these pharmaceutical products are typically pass through distributors to reach diverse healthcare facilities such as

public and private hospitals, clinics, wholesale drug stores, and pharmacies. During short-term drug shortages, wholesale drug stores take on the additional responsibility of supplying medicines to healthcare facilities and distributing medications to clinics and pharmacies experiencing lower demand. Moreover, collaborative efforts between the National Health Security Office and the Social Security Office have introduced special projects like the universal coverage and social security system. These initiatives aim to ensure widespread availability of pharmaceuticals, particularly for rare diseases, and orphan drugs such as antidotes and antivenom. The government assigns the procurement and distribution of medicines for special project to the state enterprise under its control, such as the Government Pharmaceutical Organization (Suchonwanich et al., 2020). Therefore, every stakeholder in the PSC must adhere to and meet the standards, regulations, and legislation set forth by the National Regulatory Authority (NRA). Compliance is essential at all stages of the PSC to fulfill the associated responsibilities; failure to do so may result in legal penalties.

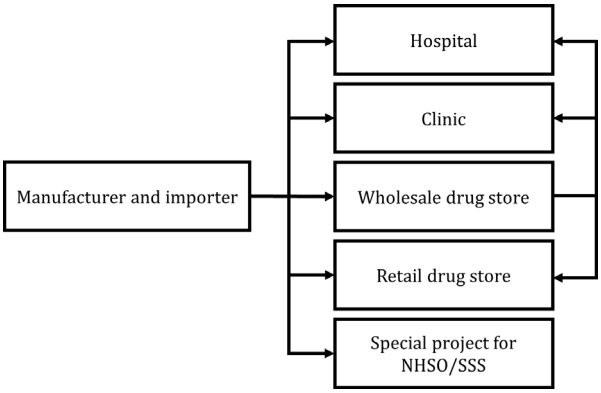

Figure 1. Drug distribution channels

As a regulatory body, the NRA has established many standards, regulations, and legislations to uphold the quality of pharmaceutical products. These include good manufacturing practices (GMP), good distribution practices (GDP), good storage and distribution practices (GSDP), and good pharmacy practices. Consequently, regulations and licensing requirements are enforced on these practices as part of pharmaceutical quality assurance programs to ensure the quality of pharmaceutical products (WHO, 2010, 2014, 2020). In Thailand, the NRA, known as the Thai Food and Drug Administration (TH-FDA), has implemented numerous measures to safeguard pharmaceutical products across the country's PSC, as illustrated in Figure 2.

As preventive measures against the entry of falsified and substandard products into the market, GSDP and GDP are essential in maintaining the quality of pharmaceutical products. These practices involve implementing rigorous controls throughout the storage and distribution processes, from manufacturers to customers. Compliance with GSDP or GDP ensure several key outcomes: (1) pharmaceutical products in the PSC comply with relevant legislations, (2) products are stored under appropriate conditions during transportation, (3) contamination by other products is prevented, (4) adequate turnover control of stored pharmaceutical products is maintained, and (5) correct products are delivered to the correct recipient within specified timeframes (EMA, 2021; WHO, 2020).

As the government agency under the Ministry of Public Health, the TH-FDA regulates most pharmaceutical activities using license systems, such as those for manufacturers, importers, and sales. These systems oversee and control the standard of operational activities, including GMP and GDP, to ensure compliance in the pharmaceutical sectors before obtaining a license and performing pharmaceutical-related operations.

Before the TH-FDA announced the GDP standard, they performed several mock inspections, particularly on biopharmaceutical drug transport, and adopted the World Health Organization (WHO) GSP and WHO GDP as guidelines for biopharmaceutical drugs, such as erythropoietin distribution. In 2016, the TH-FDA became a participating authority in the Pharmaceutical Inspection Co-operation Scheme (PIC/S), leading Thailand's guidelines to align with the PIC/S standard, including Thailand GDP (TH-GDP). Subsequently, the TH-FDA conducted on-site GDP inspections at five vaccine distributors and identified several deficiencies. In response, the TH-FDA legislated and endorsed the relevant Ministerial Regulation and Ministerial Notification on TH-GDP in 2019 and 2021. The new TH-GDP regulation has been effective since January 1, 2022, requiring full compliance from all manufacturers and importers operating in Thailand (Thai Food and Drug Administration, 2020).

To ensure consistently high product quality and protect against falsified and substandard products during storage and distribution, the TH-FDA has mandated that all pharmaceutical manufacturers and importers, including the case study company, adopt TH-GDP. As a major pharmaceutical manufacturer and importer, the case study company excels in traditional manufacturing and constantly improves manufacturing quality through the implementation of quality programs, including TH-GMP. This TH-GDP mandate can be seen as an opportunity to engage top executive and extend quality programs beyond manufacturing into logistics.

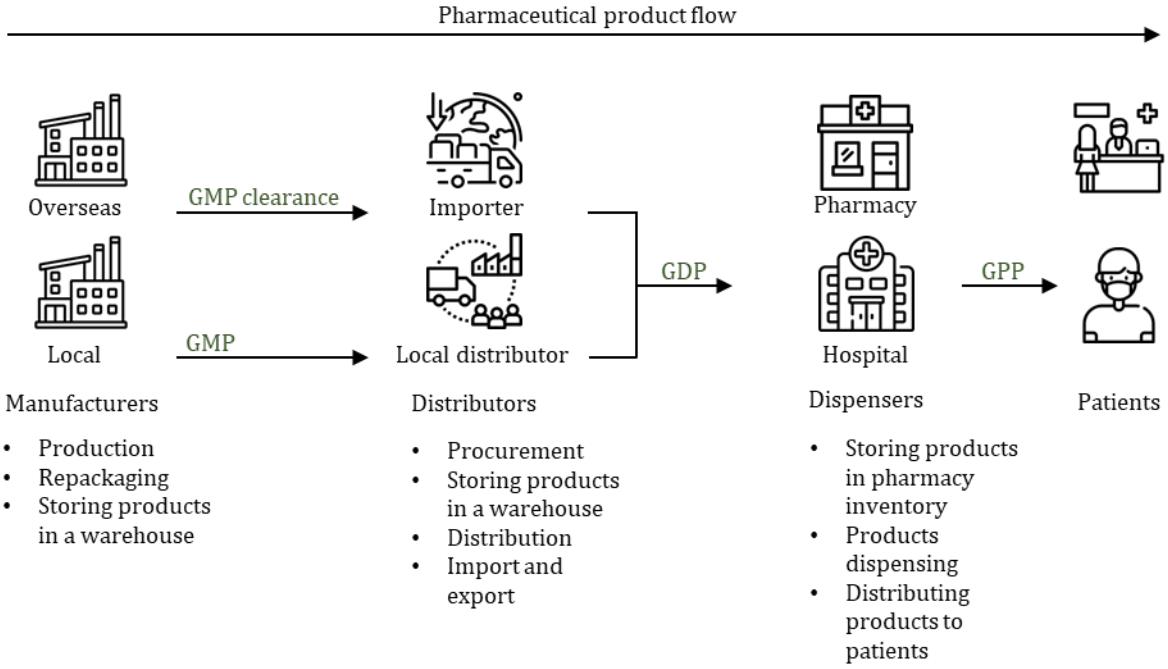

Figure 2. Pharmaceutical products flow

2. MATERIALS AND METHODS

The selection criteria for the case study company focused on Thai pharmaceutical manufacturers with integrated distribution capabilities (both in-house and outsourced) across all Thai provinces. Companies must handle at least one cold-chain product and offer a diverse range of dosage forms (e.g., solids, creams, liquids, capsules, injectables, biologicals, and vaccines). Additionally, a minimum of 100 warehouse and distribution personnel and a total workforce exceeding 1,000 are required. Furthermore, companies must have TH-FDA GMP certification and generate revenue exceeding 10 billion Thai bahts from pharmaceuticals and medical devices.

The methodology for this GDP implementation was derived from a combination of project management and risk management, particularly from a quality perspective, according to the ICH guidelines on quality risk management (QRM). As a novel project, the project management framework provides valuable tools and approaches for prioritizing operational gaps, managing expectations, and securing necessary resources. In contrast, risk management highlights the risk aspects of companies, including operation, their image, and cost. The methodology is presented in chronological order, as depicted in Figure 3, except for communication.

In Figure 3, each dashed block represents an implementation process, with individual rectangles and text next to arrows depicting the activity and outcome. For example, the risk analysis block comprises two activities: “define rubric” and “analyze risk”. the outcomes are severity rubric, probability rubric, detectability rubric, failure mode and effects analysis (FMEA) report, and risk matrix. The colors of the outcomes indicate their data sensitivity. The darker-color outcomes are shown in the next section, whereas the lighter-color ones are omitted from the article due to proprietary reasons.

The first dashed block is the project charter, which is derived from a typical project management framework. In this block, the as-is procedure was investigated and compared with PIC/S GDP and its best practice to identify the PIC/S GDP gap. The activities necessary to complete the project’s objective, scope, and due date were identified. The critical outcome is the formation of the project team, whose members serve as leaders in activities. The project team is also responsible for managing and approving the subsequent blocks. After establishing the project team and defining the project charter, the risk management process is initiated by mapping the operation process and concurrently analyzing resources, responsibilities, and stakeholders. This block is paramount as implementation emphasizes communication among stakeholders and their incentives.

As a part of risk assessment, the risk identification, risk analysis, and risk evaluation blocks aim to gather and prioritize existing risks. The risks are then grouped into accepted risks and unacceptable ones. An unaccepted risk is assigned to a responsible team, with the project team member serving as its leader. The goal of each team is to improve the risk score and risk priority number (RPN). During the risk reduction block, each team addresses its GDP noncompliance issues in a cycle. The team must schedule activities and propose milestones before executing such planned activities. Progress evaluation occurs periodically to adjust resources. Once a milestone is achieved, the team should re-evaluate the risk, referred to as a residual risk. A residual risk must undergo this cycle until it is accepted by the project team.

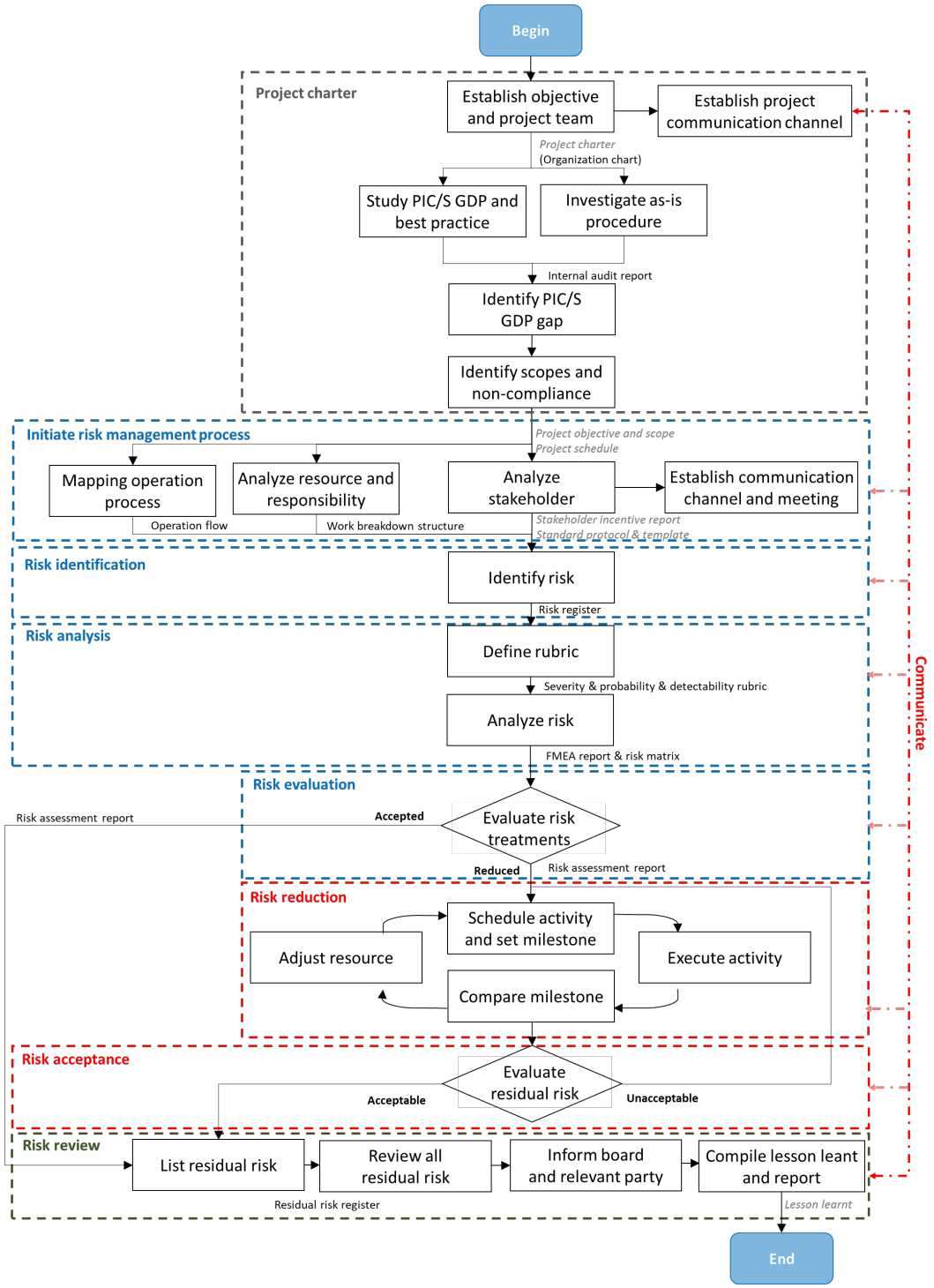

Figure 3. Activities and outcomes during the GDP implementation

The last procedure in the methodology is the risk review block, where all accepted risks are listed in the residual risk register for future reference. Before presenting to the board of directors and informing relevant parties, the project team must review the risk register to ensure operational document is comprehensiveness and coherence. The approval document is then submitted to the TH-FDA for accreditation of TH-GDP.

Throughout the project activities, communication is the core component for collaboration among the project team, company employees, and other stakeholders. The communication protocol specifies that all stakeholders must be informed using different methods based on their positions, power, and interest in the company and project. For example, the project team and supervisors must be informed by all available means; the heads and directors of internal stakeholders should be communicated with via formal meetings, direct messaging, and video clips; meanwhile, operators should be communicated with via direct informal meetings, messaging, and video clips.

2.1 Research instrument

1. PIC/S guide to good distribution practice for medicinal products (PIC/S, 2014)
2. Notification on good distribution practice requirements for modern medicines (Thai Food and Drug Administration, 2021)
3. Self-assessment checklist on GDP for modern medicinal products published by Thai Food and Drug Administration
4. Legal problems on drug quality control in the drug logistics in Thailand (Jarunsathianchai, 2015)
5. Good distribution practice inspection deficiency data from foreign country (37–38) (Bishara, 2006; Stoimenova et al., 2019)
6. ICH guideline Q9 on quality risk management (EMA, 2015)
7. A guide to the project management body of knowledge (PMBOK® guide) (Project Management Institute, 2017)
8. Failure modes and effects analysis (FMEA and FMECA) standard (International Electrotechnical Commission, 2006, 2018)

3. RESULTS AND DISCUSSION

3.1 Project charter and scope

Having received the mandate from the executive, the project team comprises the head of the GMP section, head of provincial distribution, head of central distribution, marketing officer of customer relationship management, inventory officer of the warehouse section, engineer of the GMP section, and quality assurance personnel of the GMP section, as shown in Figure 4.

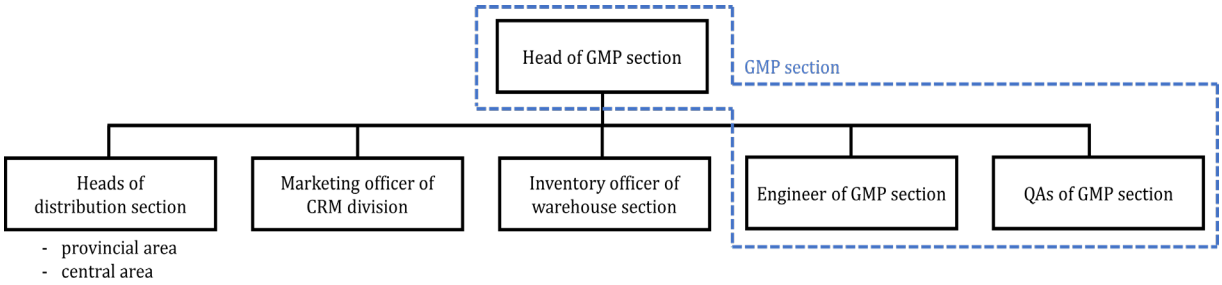

Figure 4. Project team

Most members are from the GMP section, which is the most familiar with quality assurance and quality programs. The team prioritizes and devises 4 communication prongs: formal meetings, face-to-face communication, direct messaging, and video clips. Formal meetings are held weekly to update overall progress, while face-to-face communication aims to discuss details and brainstorm solutions when teams encounter an obstacle. Direct messaging serves to update progress and engage stakeholders.

As the first phase of TH-GDP implementation, the project team focused on the outbound logistics operation because the implementation scope had been reviewed and selected internally, and the outbound operation directly affected the reputation of the company and the quality of the finished products. To identify TH-GDP gaps, the project team conducted a thorough analysis, comparing TH-GDP guidelines and checklists to current operations.

Furthermore, historical customer complaints, internal audits, operation reviews, and feedback from consultants and other accredited manufacturers were also considered. The self-assessment checklist published by the TH-FDA, divided into 9 chapters, was used for the evaluation. Each chapter was subdivided according to its contents, with each section containing a list of questions. The project team use this checklist to assess TH-GDP compliance of current operation, with 4 possible outcomes: (1) complete (C) or compliance operation, (2) incomplete (I) or noncompliance operation, (3) not available (N) or the company does not have any operation relevant to the checklist, and (4) not applicable (NA) or the company does not need to implement the operation. The incomplete (I) and not available (N) results must be revised and established according to the GDP standard. The project team uses Equation 1 to measure the percentage of completed content.

$$Percentage\ of\ content\ completion = \frac{number\ of\ complete\ results \times 100}{total\ number\ of\ results - number\ of\ NA\ results} \quad (1)$$

After measuring the content completion percentage, the number of content completions can be grouped according to the completion percentage range (i.e., 0, 1–50, 51–99, and 100) for each TH-GDP chapter, as shown in Table 1.

Table 1 shows the TH-GDP gaps in operational procedures based on current quality documents and operational workflows. For example, in TH-GDP Chapter 5, which describes operations, the project team discovered that 4 contents complied with TH-GDP, 3 contents need improvement and revised, and 1 content had to be established to comply with TH-GDP. However, Chapter 8 was completed because the company already had a self-inspection operation in place according to the GMP requirements, and the self-inspection operation for GDP is similar to that for GMP.

Table 1. Numbers of content grouped according to the completion percentage for each TH-GDP chapter

TH-GDP chapter	Numbers of content within percentage of completion range			
	0	1–50	51–99	100
0. Overall	1			
1. Quality Management	3		1	2
2. Personnel		3	1	1
3. Premises and equipment	1	4	1	1
4. Documentation			1	1
5. Operations	1	2	1	4
6. Complaints, returns, suspected falsified medicinal products and Medicinal Product Recalls	1	1	2	1
7. Outsourced activities		1		
8. Self-inspections				1
9. Transportation	3	2		

3.2 Initiation of the risk management process

Due to the complexity of the distribution process, the project team devised operation flowcharts that comply with the TH-GDP guidelines. These flowcharts serve as visualization tools for the process and shipping procedures, as shown in Figures 5 and 6. Figure 5 presents the warehouse receiving process after production; products that undergo the verification process are routed to the quality inspection (QI) or quarantine area. Products that pass the QA review are moved to the ready-for-sale storage area, whereas rejected products await disposition in the rejection area. Figure 6 illustrates the post-order fulfillment process, in which products flow from the warehouse through the distribution center (DC) to the customer, including potential returns for exchange.

For operators at a distribution center, Figures 5 and 6 show the activities, outline operation areas, and list related documents. Each activity is labeled based on the sequence in which a specific operator performs it. For example, the quarantine area in Figure 5 comprises three activities: WH2 and WH3 are performed by a warehouse operator, and QA1 is performed by the quality assurance staff. The quality assurance staff reviews and performs batch releases based on analytical reports and batch processing records. These operations and activities are generally similar to standard warehousing and distributing activities in other industrial sectors; however, the pharmaceutical sector focuses more on product quality, information traceability, and storage temperature control.

Once the complied activities were agreed upon, attention shifted to available resources and the responsibilities of related stakeholders. The project team engages in discussions and assigns the contents requiring revision to personnel involved in or directly related to the functions. A designated project team member acts as the team leader to oversee this process. Each functional team must propose the duration required to revise the assigned task (the incomplete (I) and not available (N) results according to the self-assessment checklist), as summarized in Table 2. Furthermore, each functional team must list additional resources required to complete the task; for example, Chapter 3 require premise restoration and data locker installation.

In Table 2, the minimum, mean, and maximum durations represent the minimum, average, and maximum time required to complete the task in each chapter, respectively. Although the total duration indicates the overall time required to complete all tasks in a chapter, it is not always the sum of individual task durations, as some tasks can be performed concurrently. It can be seen that significant time (>20 weeks) was allocated to outsourced activities, premises and equipment, and operations and transportation.

As a large manufacturer, the project team noticed the competing priorities of functional teams and analyzed the cost–benefit of members based on department, organizational structure, incentives, and the implementation phrase. In addition to top executives and logistics-related departments, the analysis identified underlying internal stakeholders, including the Legal Department, which reviews transportation contracts; the Pharmaceutical Production Department, which ensures that the finished product complies with GMP and GDP; and the Technology and Engineering Department, which handles construction contracts and maintains equipment and vehicles. These additional departments are crucial and influence the success of GDP implementation.

3.2.1 Risk identification and analysis

The implementation of GDP adopted the FMEA concept as a risk management tool. Each functional team identifies potential risks based on ERP historical data, process analysis, and stakeholder opinions. After identifying the risks, the project team developed and defined scoring rubrics for quantifying severity, probability, and detectability, as shown in Table 3.

For a detailed description of the scoring criteria for severity, probability, and detectability, please refer to Appendix A. The project team calculated the risk score by multiplying the severity score by the probability score. This result was then compared with the risk classification criteria in Table 4 to determine the risk class. Finally, the team calculated the RPN by multiplying the risk score by the detectability score and assigned the risk priority according to the criteria in Table 5. The risk assessment prior to project implementation is shown in Table 6.

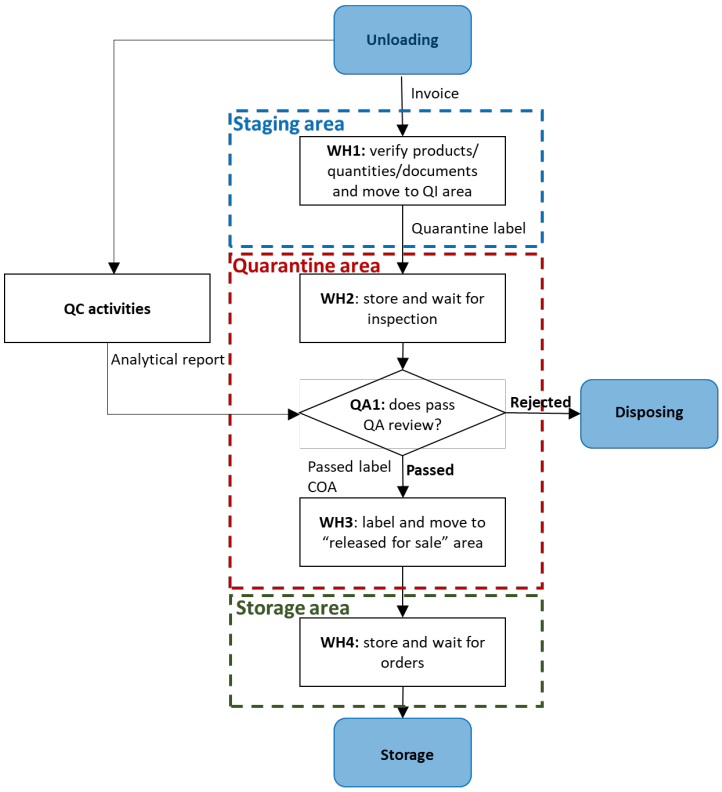

Figure 5. Receiving process at a warehouse

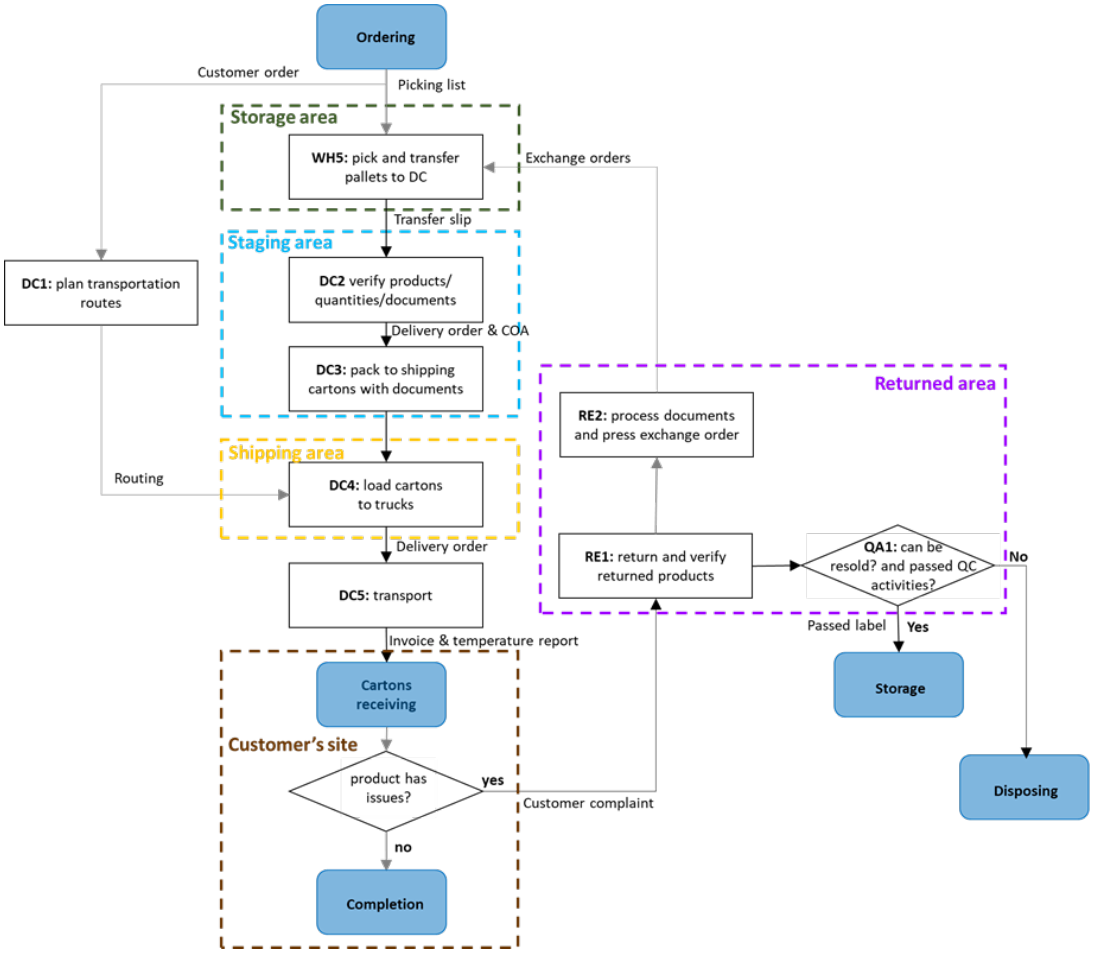

Figure 6. Picking and shipping processes at a distribution center and returning process

Table 2. Proposed implementation duration

TH-GDP chapter	Total task (I, N)	Duration (weeks)			
		min	mean	max	total
0. Overall	1	4	4	4	4
1. Quality Management	7	2	4.6	8	16
2. Personnel	9	2	3.4	4	10
3. Premises and equipment	24	2	6.1	20	36
4. Documentation	1	16	16	16	16
5. Operations	17	2	6.5	12	24
6. Complaints, returns, suspected falsified medicinal products and Medicinal Product Recalls	6	4	5.3	8	12
7. Outsourced activities	5	4	10.4	16	44
8. Self-inspections	0	0	0	0	0
9. Transportation	10	4	9.2	16	24

Table 3. Scoring and description of severity, probability, and detectability

Score	Severity (S)	Probability (P)	Detectability (D)
1	Negligible	Rarely	Very high
2	Minor	Occasionally	High
3	Moderate	Likely	Medium
4	Major	Frequently	Low
5	Critical	Continually	Very low

Table 4. Risk classification scoring

Risk classification	Score (S × P)
Unacceptable	15–25
Undesirable	5–14
Acceptable	1–4

Table 5. Risk priority scoring

Risk priority	Score (S × P)
High	75–125
Medium	21–74
Low	1–20

Table 6. Risk assessment before implementation

Process	Risk ID	Potential failure mode	Severity	Probability	Score	Risk classification	Detectability	RPN	Risk priority
WH1	WH1_01	receiving incorrect quantity of products	3	1	3	Acceptable			
	WH1_02	mismatching storage condition of products	4	2	8	Undesirable	2	16	Low
WH2	WH2_01	transporting or storing unreleased products	5	1	5	Undesirable	1	5	Low
	WH2_02	deviating storage temperature exceed acceptance limit	4	3	12	Undesirable	2	24	Medium
	WH2_03	damaging storage products from air condition leakage	3	3	9	Undesirable	2	18	Low
	WH2_04	damaging storage products from insects and pests	3	2	6	Undesirable	3	18	Low
	WH2_05	damaging storage products from crash or friction	3	3	9	Undesirable	2	18	Low
	WH2_06	products lost/stolen	4	1	4	Acceptable			
WH4	WH4_01	deviating storage temperature exceed acceptance limit	4	3	12	Undesirable	2	24	Medium
	WH4_02	damaging storage products from air condition leakage	3	3	9	Undesirable	2	18	Low
	WH4_03	damaging storage products from insects and pests	3	2	6	Undesirable	3	18	Low
	WH4_04	damaging storage products from crash or friction	3	3	9	Undesirable	2	18	Low
	WH4_05	products lost/stolen	4	1	4	Acceptable			
WH5	WH5_01	picking incorrect products	3	3	9	Undesirable	2	18	Low
	WH5_02	partial/incomplete picking of products	3*	2	6	Undesirable	2	12	Low
	WH5_03	picking incorrect production lots specific by customers	3*	2	6	Undesirable	5	30	Medium
	WH5_04	picking incorrect production lots specific by system	3*	3	9	Undesirable	2	18	Low
	WH5_05	violating FEFO principle	4	1	4	Acceptable			
	WH5_06	violating FEFO principle, despite customer's request	4	4	16	Unacceptable	2	32	Medium
DC3	DC3_01	deviating product temperature exceed acceptance limit	4	5	20	Unacceptable	5	100	High
	DC3_02	misusing/ improper using of packaging	4	3	12	Undesirable	2	24	Medium
	DC3_03	package of product broken	3	3	9	Undesirable	5	45	Medium

Table 6. Risk assessment before implementation (continued)

Process	Risk ID	Potential failure mode	Severity	Probability	Score	Risk classification	Detectability	RPN	Risk priority
	DC3_04	incorrect packing or misplacing products	3*	3	9	Undesirable	2	18	Low
	DC3_05	products lost/stolen	4	1	4	Acceptable			
	DC3_06	fail to prepare relevant documents	3*	3	9	Undesirable	2	18	Low
DC4	DC4_01	Incorrect loading or misplacing products	3*	3	9	Undesirable	2	18	Low
	DC4_02	deviating loading-dock temperature exceed acceptance	4	5	20	Unacceptable	5	100	High
DC5	DC5_01	deviating transporting temperature exceed acceptance	4	4	16	Unacceptable	5	80	High
	DC5_02	damaging transported products from air condition leakage	3	1	3	Acceptable			
	DC5_03	damaging transported products from transportation	3	1	3	Acceptable			
	DC5_04	damaging transported products from air condition leakage by logistics provider	3	4	12	Undesirable	2	24	Medium
	DC5_05	damaging transported products from negligent by logistics provider	3	4	12	Undesirable	2	24	Medium
	DC5_06	damaging transported products from air condition breakdown by logistics provider	4	4	16	Unacceptable	5	80	High
	DC5_07	fail to delivery products as scheduled by logistics provider	3*	4	12	Undesirable	2	24	Medium
	DC5_08	fail to delivery products with suitable transportation mode	4	4	16	Unacceptable	5	80	High
	DC5_09	outsourcing transportation to unauthorized logistics provider	4	3	12	Undesirable	5	60	Medium
	DC5_10	fail to record transporting temperature by logistics provider	4	3	12	Undesirable	5	60	Medium
	DC5_11	products lost during transportation by logistics provider	3*	4	12	Undesirable	5	60	Medium
	DC5_12	products stolen by logistics provider	4	1	4	Acceptable			
RE1	RE1_01	no temperature record during return transportation	4	5	20	Unacceptable	2	40	Medium
	RE1_02	fail to control temperature during return transportation	4	2	8	Undesirable	3	24	Medium
	RE1_03	partial/incomplete temperature control during return transportation	4	3	12	Undesirable	3	36	Medium

Note: *Severity assessed by company's image instead of operation.

Table 6 describes the potential failure mode (risk events), along with their probability and severity scores. The multiplication of these scores is referred to as the risk scores, serving as the risk classification and forming the risk matrix (Chongprasert, 2020), as shown in Figure 7.

Acceptable risk event requires no further action or specific detection. However, undesirable and unacceptable risk events require detectability scoring. Multiplying the risk score by the detectability score yields the RPN, an important FMEA index that reflects the resources and urgency required for addressing a risk event. A higher RPN indicates greater urgency and resource intensiveness.

3.2.2 Risk reduction

The project team required each functional team to propose a control activity. These proposals, along with their corresponding milestones, were presented, discussed, and approved before implementation. Generally, risk reduction efforts can be categorized into 6 areas: reviewing procedures and work instructions, reviewing operation flows, adding check and verification processes, training operators, communicating with customers, and renovating related facilities and premises. Note that risk reduction focuses on reducing the probability or increasing the detectability of risk events, rather than reducing severity, because the QRM approach does not alter the fundamental nature of risk events.

3.2.3 Risk review

After risk reduction, most risk scores and RPN fall within the acceptable range, as shown in Tables 7 and 8.

The transition matrix illustrates the number of risk events before and after risk reduction, based on their risk classification and RPN. For example, out of 28 undesirable risk events before risk reduction, 4 were reclassified as acceptable, while the remaining events retained their original classification. Notably, 8 risk events had been classified as acceptable before risk reduction, which meant they had no detectability scores and no RPN. In Table 8, the RPNs of 10 risk events were reduced from medium to low, the RPNs of 4 risk events were reduced from high to low, and the RPN of 1 risk event was reduced from high to medium. The project and functional teams invested significant resources and person-hours to enhance the detectability of risk events and reduce their probability. Despite these efforts and the managerial pressures involved, some risks had to accepted. For example, case RE1_01 in Table 6 involves the customer storage issues affecting the business. Consequently, the decision was made to accept all returned products with or without storage

temperature data, though the manufacturer is required to dispose of products lacking temperature data.

After listing all residual risk events, the project team assigned a QA division to review all procedures and ensure compliance across all quality programs. This review highlighted the availability of documentation and records. As a part of GDP, a self-inspection was performed and revealed that some stakeholders may not have followed the updated procedures correctly due to their familiarity with the old procedures. The QA division was then continuously monitored and enforced before submitting the audit request to the TH-FDA. In the last quarter of 2022, the case study company received accreditation from the TH-GDP. Throughout the implementation process, the company reflected on the GDP implementation and gained valuable business insights. These lessons are valuable for the next phase of implementation, particularly in procurement and raw material handling, as the distribution and storage of raw materials impact product quality.

		Severity				
		Negligible	**Minor**	**Moderate**	**Major**	**Critical**
Probability	**Continually**				**DC3_01 DC6_02 RE1_01**	
	Frequently			DC7_04 DC7_05 DC7_07 DC7_11	**WH7_06 DC7_01 DC7_06 DC7_08**	
	Likely			WH3_03 WH3_05 WH6_02 WH6_04 WH7_01 WH7_04 DC3_03 DC3_04 DC3_06 DC6_01	WH3_02 WH6_01 DC3_02 DC7_09 DC7_10 RE1_03	
	Occasionally			WH3_04 WH6_03 WH7_02 WH7_03	WH2_02 RE1_02	WH3_01
	Rarely			WH2_01 DC7_02 DC7_03	WH3_06 WH6_05 WH7_05 DC3_05 DC7_12	

Figure 7. Risk matrix of potential failure mode (risk events)

Table 7. Transition matrix of risk classification before and after risk reduction

		After risk reduction			Total
		Acceptable	**Undesirable**	**Unacceptable**	
Before risk reduction	**Acceptable**	8			8
	Undesirable	4	24		28
	Unacceptable	2	4	1	7
Total		14	28	1	43

Table 8. Transition matrix of RPN before and after the risk reduction

		After risk reduction			Total
		Low	**Medium**	**High**	
Before risk reduction	**Low**	14			14
	Medium	10	6		16
	High	4	1		5
Total		28	7		35

3.3 Discussion

Many pharmaceutical manufacturers, including the case study company, have implemented GDP to safeguard product quality during storage and distribution. The first phase of GDP implementation incorporates project management and risk management to the outbound logistics process. After implementation, the manufacturer recognized that a quality program build upon one another. Specifically, GMP certification overlaps with and provides a strong foundation for GDP implementation, particularly in terms of the documentation framework and quality management system (QMS) methodology. The principles of GMP and GDP support patient safety, regulatory compliance, and streamlined manufacturing and distribution processes. Without GMP implementation, the manufacturer would need to allocate significant resources, establish the GMP/GDP process, and hire QMS specialists to handle GDP implementation.

Due to the prompt nature of the implementation, the project team had to continually facilitate and communicate precise activities to all functional teams. Fortunately, this top–down project management approach aligned with the bureaucratic nature of the case study company, which was critical for engaging stakeholders and disseminating the benefits. Otherwise, the implementation would have encountered resistance. After implementing the outbound logistics process, the project team suggests 4 critical lessons for future implementation: (1) improving project management culture, (2) reviewing and utilizing project management templates and tools, (3) continuously monitoring GMP and GDP, and (4) streamlining activities with information technology systems.

4. CONCLUSION

The implementation of TH-GDP was facilitated by integrating well-structured project management and risk management methodologies. This achievement resulted directly from the collaborative efforts of stakeholders within the case study company. Notably, this effort led to positive outcomes and a significant reduction in the TH-GDP gap. In term of risk management, the process significantly improved risk categorization. The collaborative approach to information sharing within the project team during risk identification and management played a pivotal role in the seamless execution of GDP and QRM implementation.

Stringent quality assurance was enforced, involving the project and QA teams to ensure the thoroughness and compliance of documents and reports. The company was accredited by the TH-FDA in 2022. Ultimately, this project met its predefined objectives and gathered valuable insights and knowledge, enhancing the company's overall project management capabilities.

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APPENDIX A

Severity

Name	Score	Description		
		Operation	Company's image	Cost (Baht)
Negligible	1	No impact on product nor process robustness. Effect unnoticeable by patient.	No impact on corporate image. No news in social feeds.	<10,000
Minor	2	No impact on product safety. Limited impact on product quality and efficacy. Limited impact on operations.	No impact on corporate image. No news in social feeds.	10,000–50,000
Moderate	3	Limited impact on product safety and efficacy. Noticeable impact on product quality. Limited product recall possible.	Limited impact on corporate image. Limited news in social feeds.	50,000–250,000
Major	4	Impact on product safety and efficacy, but not pervasive. Cause reversible side effects. Major deviation from GMDP requirement. Regulatory authorities need to be engaged. Recall product from limited markets.	Noticeable impact on corporate image. Highly spread of news in a social feed.	250,000–1,000,000
Critical	5	Catastrophic impact, significant losses, and inefficiency in the process. Critical deviation from GMDP requirement. Recall products from all markets, globally.	Catastrophic impact on corporate image. Wildly spread of news in television and newspaper.	>1,000,000

Probability

Name	Score	Description
Rarely	1	Occurred no more than once every 3 years
Occasionally	2	Seen between 2–3 years
Likely	3	Seen every year
Frequently	4	Seen between 1–6 months, but not >5 times a year
Continually	5	Seen every or less than a month

Detectability

Name	Score	Description
Very high	1	Automatic detection mechanism has been installed and applies to every product.
High	2	Detection mechanism has been installed and applied to some products.
Medium	3	Detection technique can be performed upon a request.
Low	4	Detection techniques can be performed; however, the result is not conclusive.
Very low	5	Unable to detect before the incident reaches media or customers.