Self-Assessment Checklist on GDP for Modern Medicinal Products

แบบฟอร์มรายการประเมินตนเอง ตามหลักเกณฑ์วิธีการที่ดีในการกระจายยาแผนปัจจุบัน

กลุ่มกำกับดูแลหลังออกสู่ตลาด กองยา
สำนักงานคณะกรรมการอาหารและยา
ฉบับที่ 01

Post-marketing Control Sub-division,
Medicines Regulation Division,
Food and Drug Administration

Version 01

คำชี้แจง

เอกสารฉบับนี้ จัดทำขึ้นเพื่ออำนวยความสะดวกให้แก่ผู้ที่เกี่ยวข้อง ซึ่งต้องปฏิบัติตามประกาศกระทรวงสาธารณสุข เรื่อง หลักเกณฑ์ วิธีการ และเงื่อนไขในการกระจายยาแผนปัจจุบัน พ.ศ... โดยเฉพาะผู้รับอนุญาตผลิตยาแผนปัจจุบันและผู้รับอนุญาตนำหรือสั่งยาแผนปัจจุบันฯ โดยสามารถใช้เป็นเครื่องมือหนึ่งในการประเมินสถานะหรือศักยภาพขององค์กรในปัจจุบันว่ามีความพร้อมในการที่จะปฏิบัติตามหลักเกณฑ์วิธีการที่ดีในการกระจายยา (Good Distribution Practice; GDP) มากน้อยเพียงใด และจำเป็นที่จะต้องปรับปรุงหรือพัฒนาในด้านใดเพิ่มเติม เพื่อยกระดับมาตรฐานในการควบคุมและดูแลผลิตภัณฑ์ยาให้มีคุณภาพและปลอดภัยในการใช้ตลอดห่วงโซ่ผลิตภัณฑ์

ทั้งนี้ เอกสารแบบฟอร์มรายการประเมินตนเองตามหลักเกณฑ์วิธีการที่ดีในการกระจายยาแผนปัจจุบัน (Self-Assessment Checklist on GDP for Modern Medicinal Products) แบ่งเป็น 2 ส่วนหลักคือ ส่วนที่ 1 ข้อมูลทั่วไป และส่วนที่ 2 การประเมินตนเองตามหมวดต่าง ๆ ที่กำหนด โดยวิธีการหรือเงื่อนไขในการกรอกข้อมูลในเอกสารฉบับนี้เป็นไปตามรายละเอียดที่ปรากฏในคู่มือการใช้งาน

คณะผู้จัดทำหวังเป็นอย่างยิ่งว่าเอกสารฉบับนี้จะเป็นประโยชน์และเป็นส่วนหนึ่งในการเสริมสร้างความรู้ ความเข้าใจเกี่ยวกับหลักการสำคัญและแนวทางปฏิบัติตามหลักเกณฑ์วิธีการที่ดีในการกระจายยา (Good Distribution Practice; GDP) และหากมีข้อผิดพลาดประการใดต้องขออภัยมา ณ ที่นี้ด้วย

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สารบัญ

หน้า

คู่มือการใช้งาน

Instruction for Filling out
Self-Assessment Checklist on GDP for Modern Medicinal Products

ส่วนที่ 1 ข้อมูลทั่วไป (Part of Administration)

ให้ระบุข้อมูลพื้นฐานเกี่ยวกับองค์กรของตน ได้แก่ ชื่อสถานที่ ประเภทใบอนุญาต เลขที่ใบอนุญาต ประเภทของกิจกรรม ชนิดของผลิตภัณฑ์ สภาวะการจัดเก็บ กิจกรรมการจ้างบุคคล/หน่วยงานภายนอก

ส่วนที่ 2 การประเมินตนเองตามหมวดต่าง ๆ ที่กำหนด (Part of Self-assessment regarding Requirements of Each Chapter)

1. ให้พิจารณาประเด็นหลักและคำถามที่ระบุไว้ในช่อง “List of Questions”
2. ให้พิจารณาตัวเลือกและระบุคำตอบในช่อง “Response” ตามข้อเท็จจริง โดยอักษรย่อซึ่งเป็นตัวเลือกมีความหมายดังนี้

   C = Complete = มี/จัดทำไว้ อย่างครบถ้วน สมบูรณ์

   I = Incomplete = มี/จัดทำไว้ แต่ยังไม่ครบถ้วน สมบูรณ์

   N = Not available = ไม่มี/ไม่ได้จัดทำไว้

   N/A = Not applicable = ไม่จำเป็นต้องมี/ไม่จำเป็นต้องจัดทำ
3. สำหรับบางกิจกรรมที่อาจมี/ไม่มีการจ้างบุคคล/หน่วยงานภายนอก ให้พิจารณาตัวเลือกและระบุคำตอบในช่อง “Outsourced” ตามข้อเท็จจริง โดยอักษรย่อซึ่งเป็นตัวเลือกมีความหมายดังนี้

   Y = Yes = มีการจ้างบุคคล/หน่วยงานภายนอกเพื่อทำกิจกรรมนั้น

   N = No = ไม่มีการจ้างบุคคล/หน่วยงานภายนอกเพื่อทำกิจกรรมนั้น

   P = Partially = มีการจ้างบุคคล/หน่วยงานภายนอกเพื่อทำกิจกรรมนั้น ๆ ในบางส่วน
4. ช่อง “Remarks” อาจไม่จำเป็นต้องระบุ แต่หากประสงค์ที่จะระบุข้อมูลต่าง ๆ ที่เกี่ยวข้องสำหรับประเด็น/หัวข้อนั้น ๆ ก็สามารถระบุได้ เช่น รายการเอกสารหรือเอกสารอ้างอิงที่เกี่ยวข้อง
5. ช่อง “PIC/S Reference” เป็นการแสดงข้อมูลอ้างอิงว่าคำถามที่ระบุไว้ในช่อง “List of Questions” สอดคล้องกับหลักเกณฑ์ข้อใดของ PIC/S Guide to Good Distribution Practice for Medicinal Products (PE 011-1, 1 June 2014)

Self-Assessment Checklist on GDP for Modern Medicinal Products

Part of Administration

Company name	
License type	( ) Manufacturing of Modern Medicinal Products ( ) Importing of Modern Medicinal Products For ( ) Human use ( ) Veterinary use
License No.	

	Yes	No	Remarks
Type of Activity			
Manufacturer			
Importer			
Wholesaler			
Holding/Storage			
Distribution			
Contracted operation - Holding/Storage			
Contracted operation - Distribution			
Medicinal Products Handled (Legal Category)			
Finished medicinal products			
Intermediate medicinal products			
Active pharmaceutical ingredients			
Excipients			
Others (please specify in remarks)			
Medicinal Products Handled (Risk Category)			
Sterile products			
Non-sterile products			
Biologics			
Cytotoxics			
Penicillins and/or Cephalosporins			
Sex hormones			
Others (please specify in remarks)			
Storage Condition			
Below 25°C or 30°C			
Cold chain			
Outsourced Activities (Please list below if any)			

1. Quality Management

List of Questions	Response C, I, N or N/A	Outsourced Y, N or P	Remarks	PIC/S Reference
Quality System				
Do you have Quality Manual?				1.2.2
Change Control				
Is procedure available?				1.2.6
Has Log of change requests been available since last 3 years?				1.2.6
Is classification in accordance with quality risk management principles?				1.5
Were the changes notified to and approved by the relevant authorities, if it was required?				1.2.1
Deviation Management				
Is procedure available?				1.2.7
Has Log of deviations been available since last 3 years?				1.2.7
Is classification in accordance with quality risk management principles?				1.5
Have appropriate CAPAs been taken to correct and prevent deviations?				1.2.7
Management of Outsourced Activities				
Have the principles of quality risk management been incorporated?				1.3, 7.1
Do you have procedure to approve a service provider?				1.3, 7.2.2
Is there a system for monitoring and review of the performance contract acceptors?				1.3, 7.2.2
Management Review and Monitoring				
Is outcome of review documented?				1.4
Quality Risk Management				
Have the principles been incorporated into the company's management of change, deviations, complaints, outsourced activities?				1.5
Did you identify which processes that pose a risk to the quality of the product?				1.5

2. Personnel

List of Questions	Response C, I, N or N/A	Outsourced Y, N or P	Remarks	PIC/S Reference
General				
Is organization chart available?				1.2.1, 2.2.2
Do you have number of persons involved in each operation?				2.2.1
Are Job Descriptions available for key personnel?				1.2.3, 2.2.3
Designation of Responsibilities				
Does the job description reflect the key responsibilities?				2.3.1, 2.3.3, 2.3.4, 2.3.5
Is the 24 hrs. contact available in case of emergency?				2.3.2
GDP Training				
Have relevant personnel received training in GDP?				2.4.1, 2.4.2
Are records available?				2.4.5
Are evaluations conducted and documented?				2.4.5
Is there a program for regular periodic training in GDP?				2.4.2
Does the training program include aspects related to falsified medicinal products?				2.4.3
Is specific training provided related to temperature-sensitive products and controlled drugs?				2.4.4
Training in Written Procedures (SOPs)				
Has personnel received training in SOPs relevant to their role?				2.4.2
Are evaluations conducted and documented?				2.4.5
Is training provided in updated revisions to SOPs?				2.4.2
Hygiene				
Is there a procedure in place covering health, hygiene and clothing requirements?				2.5

3. Premises and Equipment

List of Questions	Response C, I, N or N/A	Outsourced Y, N or P	Remarks	PIC/S Reference
Premises				
Are there adequate lighting and ventilation on storage areas?				3.2.1
Is the written contract available, in case of outsourced premises?				3.2.2
Is access to storage areas appropriately restricted to authorized personnel?				3.2.3, 3.2.8
Segregation				
Are rejected products, expired products and recalled products physically segregated?				3.2.4
Are falsified medicinal products physically segregated?				3.2.4
Are products unauthorized for the approved market physically segregated?				3.2.4
Are these areas clearly identified?				3.2.4
Are controlled drugs stored in accordance with national legislation?				3.2.5
Are radioactive materials and other hazardous products stored in accordance with national legislation?				3.2.6
Are the procedures and controls for management of inbound and outbound goods appropriate?				3.2.7
Cleaning and Pest Control				
Are there cleaning procedures and records available?				3.2.9
Is there a pest control program in place?				3.2.10
Are records available?				3.2.10
Are the rest, wash and refreshment areas appropriately segregated?				3.2.11
Temperature and Environment Control				
Are the environmental conditions monitored and are records available?				3.3.1
Has temperature mapping been conducted?				3.3.2
Were any hot spots or cold spots identified?				3.3.2
Are these locations routinely monitored?				3.3.2

3. Premises and Equipment

List of Questions	Response C, I, N or N/A	Outsourced Y, N or P	Remarks	PIC/S Reference
Is there a procedure in place for handling/management of excursions and according to the written procedure?				3.3.1
Equipment				
Is there a program/schedule in place for planned maintenance?				3.4.1
Are records available?				3.4.1
Is there a program/schedule in place for calibration?				3.4.2
Are there calibrations traceable to national/international standards?				3.4.3
Are records available?				3.4.5
Are alarm/alert systems in place to highlight excursions?				3.4.3
Is there a procedure to assess the potential impact on product as a result of the equipment failure?				3.4.4
Computerized Systems				
Is there a list of computerized systems available?				3.5.2
Are systems validated or tested?				3.5.1
Are detailed descriptions of the systems including diagrams available?				3.5.2
Are appropriate security controls in place to prevent unauthorized access?				3.5.3
Is access to stored data checked on a periodic basic?				3.5.4
Are back-up procedures in place?				3.5.4
Is there a procedure for disaster recovery of data?				3.5.5
Qualification and Validation				
Has the company identified which equipment is required to be qualified and validated?				3.6.1

3. Premises and Equipment

List of Questions	Response C, I, N or N/A	Outsourced Y, N or P	Remarks	PIC/S Reference
Have principles of quality risk management been used to determine extent of qualification and validation required?				3.6.1
Are the risk assessments available?				3.6.1
Are the qualification/validation reports available?				3.6.3
Have deviations been recorded and addressed?				3.6.3
Have appropriate approvals been obtained?				3.6.3

4. Documentation

List of Questions	Response C, I, N or N/A	Outsourced Y, N or P	Remarks	PIC/S Reference
Procedures				
Are there procedures of all key operations available?				4.2.1
Are procedures approved by relevant personnel?				4.2.4
Is version control in place?				4.2.8
Are procedures available in the work areas?				4.2.7
Are procedures reviewed periodically?				4.2.8
Records				
Are appropriate controls in place for updating or up versions of documents?				4.2.8
Are invoices available for purchases and sales?				4.2.9
Is all of the required information documented to ensure traceability?				4.2.9

5. Operations

List of Questions	Response C, I, N or N/A	Outsourced Y, N or P	Remarks	PIC/S Reference
Qualification of Suppliers				
Is there a list of approved suppliers for a defined period (e.g. last two years)?				5.1
Is there a procedure for supplier qualification/approval?				5.2.3
Have checks been done to verify the authority of suppliers to supply the particular classifications of medicinal products received?				5.2.1, 5.2.2
Have 'due diligence' checks been conducted?				5.2.4
Are periodic checks conducted using the principles of quality risk management?				5.2.3
Are records of the above checks available?				5.1
Qualification of Customers				
Is there a list of approved customers for a defined period (e.g. last two years)?				5.1
Is there a procedure for customer qualification and approval including requirements for the opening of a new account?				5.1, 5.3.1, 5.3.2
Have checks been done to verify the authority of customers to receive the particular classifications of medicinal products supplied?				5.1, 5.3.1, 5.3.2
Do you have the records?				5.1
Are periodic checks conducted using the principles of quality risk management?				5.3.2
Are records of the above checks available?				5.1
For products at risk of diversion, is there a monitoring system for sale?				5.3.3
Is there a procedure for investigating irregularities in sales patterns?				5.3.3
Are records available?				5.1

5. Operations

List of Questions	Response C, I, N or N/A	Outsourced Y, N or P	Remarks	PIC/S Reference
Receipt of Medicinal Products				
Is there a procedure in place for good receipt?				5.1
Are records available?				5.1
Are there checks to ensure goods have been authorized for sale before moving into saleable stock?				5.4.1, 5.4.3
For products with special storage requirements, are checks conducted at receipt to ensure correct storage conditions have been maintained during transportation?				5.4.1, 5.4.2
Are records available?				5.1
Is there a procedure for handling non-conforming product at receipt?				5.4.4
Storage				
Is stock rotated in accordance with FEFO principle?				5.5.4, 5.7
Is there a system in place to ensure products expired or nearing expiry date are removed for saleable stock?				5.5.6
Is product all stored off the floor?				5.5.5
Are stock inventories checked periodically and appropriate investigation of irregularities conducted?				5.5.7
Are records available?				5.1
Are procedures in place for handling products with special storage conditions?				5.5.1, 5.5.3
Fridge/Cold Store				
Has temperature mapping been conducted?				5.5.1, 3.3.2
Are the temperature monitoring devices positioned in the correct locations?				5.5.1, 3.3.2
Have the temperature monitoring devices been calibrated in the appropriate range?				5.5.1, 3.4.2
Is the continuous temperature monitoring data available?				5.5.1, 3.3.1
Are temperature alarms installed?				5.5.3, 3.4.3

5. Operations

List of Questions	Response C, I, N or N/A	Outsourced Y, N or P	Remarks	PIC/S Reference
Is there a procedure for handling temperature excursions?				5.5.3, 1.2.7
Is there a back-up system in the event of fridge/cold room failure?				5.5.3, 3.4.4
Is there an area identified for storage of product quarantine?				5.4.3, 3.2.3
Destruction of Obsolete Goods				
Is there a procedure for handling material for destruction?				5.6.1
Is it appropriately segregated and labeled?				5.6.1
Is the procedure in accordance with regulation?				5.6.2
Are records available for products which have been destroyed?				5.6.3
Picking				
Are controls in place to ensure correct product is picked?				5.7
Is there a check to ensure sufficient shelf life remaining?				5.7
Supply				
Have delivery notes, packing lists been provided with products supplied?				5.8
Are records available?				5.8
Import and Export				
Are procedures in place for import and export activities?				5.9

6. Complaints, Returns, Suspected Falsified Medicinal Products and Medicinal Product Recalls

List of Questions	Response C, I, N or N/A	Outsourced Y, N or P	Remarks	PIC/S Reference
Complaints				
Is there a procedure for handling complaints and who is responsible?				6.1, 6.2.3, 6.2.4
Have complaints been recorded and investigated?				6.1
Do you exhibit vigilance for falsified medicinal products when assessing complaints?				6.4.3
Do you classify complaints in case of a product quality defects?				6.2.1
Are there any criteria to close an investigation of complaints?				6.1
Returned Medicinal Products				
Do you have the dedicated returns area?				6.1, 6.3.1, 3.2.4
Do you have a procedure for handling returns?				6.1, 6.3.1
Is this procedure risk based?				6.3.2, 6.3.3
Do you perform assessment of returned products?				6.3.2
Do you have the returns log?				6.3.1, 6.3.2
Do you assign responsible person in different stages of the returns process?				6.1, 2.3.5
Do you handle returns of products requiring specific storage conditions?				6.3.3
Do you apply FEFO for returned products?				6.3.4
Falsified Medicinal Products				
Do you have procedures that cover vigilance against falsified medicinal products?				6.1, 6.4.2, 6.4.3
Do you have a list of products where the risk of falsification is higher?				6.4.2
Do you have paper/documentation audit trail for purchase of high-risk products from other wholesalers?				6.4.2

6. Complaints, Returns, Suspected Falsified Medicinal Products and Medicinal Product Recalls

List of Questions	Response C, I, N or N/A	Outsourced Y, N or P	Remarks	PIC/S Reference
Can you track the product ownership in relation to movement?				6.4.2
Do you check/review the dispatch documents vs receiving documents?				6.4.2, 5.5.7
Falsified Products in Returns				
Do you have procedure to protect from falsified medicinal products in returns?				6.4.2, 6.3.1
Medicinal Product Recalls				
Do you have the procedure for handling recalls?				6.1, 6.5.1
Do you have the recall log?				6.5.9
Do you ensure availability 24 hours contact for rapid alert?				6.1, 2.3.2
Do you communicate recalls to customers?				6.5.2
Do you train your staffs about the roles of involved staff during a recall?				2.4.2
Do you train your staffs regarding to discuss with the competent authority/marketing authorization holder before any recall action undertaken?				6.5.3, 2.4.2
Do you handle and segregate recalled product in your warehouse?				3.2.4
Do you have a final report including reconciliation?				6.5.9
Do you challenge your recall procedure? (e.g. mock recall)				6.5.4

7. Outsourced Activities

List of Questions	Response C, I, N or N/A	Outsourced Y, N or P	Remarks	PIC/S Reference
Outsourced Activities				
Are audits allowed in contract?				7.2.2
Do you have audits plan?				7.2.2
Are responsibilities clear in contracts?				7.1, 7.2.1
Do you ensure that no work is handed off to a third party without your knowledge?				7.3.3
Is there a process to manage the quality of products or services?				7.2.3, 7.3.5
Are there records available?				7.3.1
Are there records of cases where the quality of product or service was in question?				7.3.5

8. Self-inspections

List of Questions	Response C, I, N or N/A	Outsourced Y, N or P	Remarks	PIC/S Reference
Self-inspection				
Do you have procedures for self-inspection?				8.1
Do you have self-inspection plan?				8.2.1
Do you have the evidence that the self-inspection was completed according to plan?				8.2.1, 8.2.2
Are your auditors trained?				8.2.2, 2.4.2
Do you ensure that all found deficiencies have been addressed by CAPA?				8.2.3

9. Transportation

List of Questions	Response C, I, N or N/A	Outsourced Y, N or P	Remarks	PIC/S Reference
Responsibility				
Do you have temperature monitoring data for shipments?				9.1.1, 9.1.2, 9.4.4
Do you have transportation plan?				9.2.5, 9.4.8
Are drivers trained in GDP?				2.4.1, 2.4.2
Do they have access to relevant written procedures?				4.2.7
Storage Conditions during Transportation				
Are storage conditions ensured during transportation?				9.2.1, 9.3.1
Do you have procedures in case if they are not upheld?				9.2.2
Do you have procedures when conditions are upheld in hubs or reloading during transportation?				9.2.9
Vehicles and Equipment				
Is equipment maintained and calibrated?				9.2.4, 9.2.5
Has temperature mapping been performed?				9.4.4, 9.2.3
Containers, Packaging and Labeling				
Do you have procedure to select packaging for your transportations?				9.3.1, 9.3.2
Do you have procedures for cool packs handled?				9.4.6, 9.4.7, 9.4.8
Products Requiring Controlled Conditions				
If products at high risk for theft handled, do you have procedures to manage them?				9.4.1
If highly toxic or radioactive products handled, do you have procedures to manage them?				9.4.2
If temperature sensitive products handled, do you have procedures to manage them?				9.4.3, 9.4.8