衛生福利部食品藥物管理署103年委辦計畫
「提升藥品GMP/GDP管理制度與國際接軌」主題論壇

國際藥品GDP實施現況

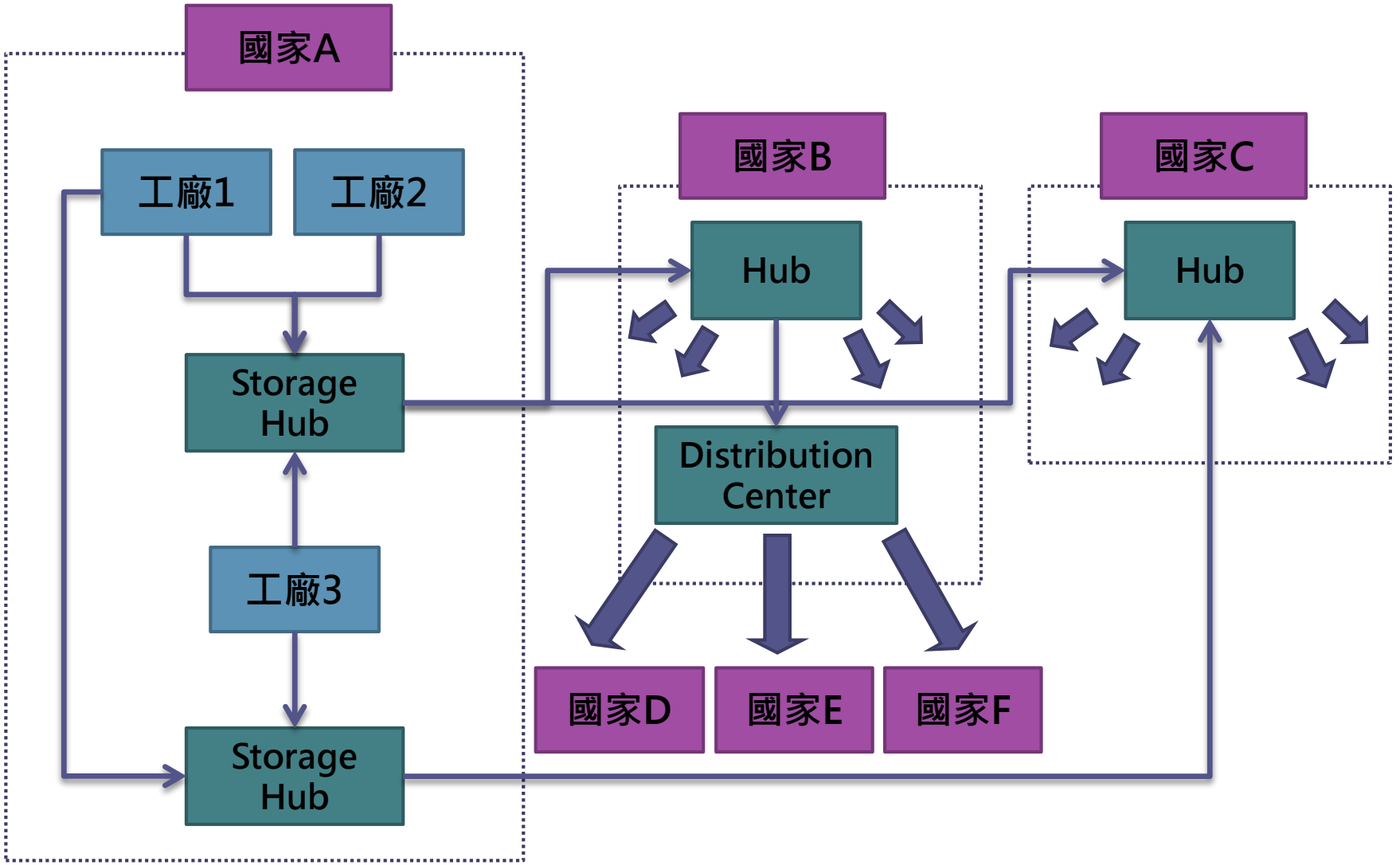
日期：103年 09月 09日 13:30~17:00
地點：政大公企中心 C601演講廳
報告人：徐卉葶

大綱

- 國際藥品GDP簡介
- 國際藥品GDP常見缺失

國際藥品GDP簡介

藥品供應鏈

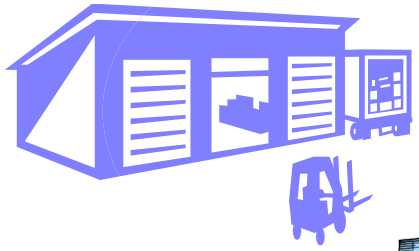

國家A
工廠1
工廠2
Storage Hub
工廠3
Storage Hub
國家B
Hub
Distribution Center
國家C
Hub
國家D
國家E
國家F

運銷網絡→複雜、動態

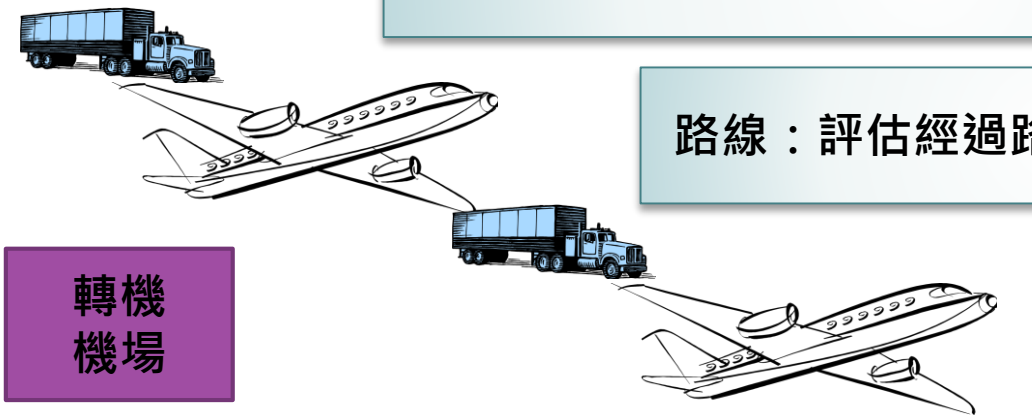
運送者：挑選運送者、運送流程規劃、挑選轉機機場

包裝：產品安定性、成本、路線、確效

路線：評估經過路線、停留機場評估

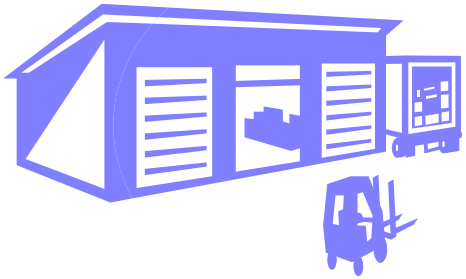


供應商
倉庫



轉機
機場

目的地
機場

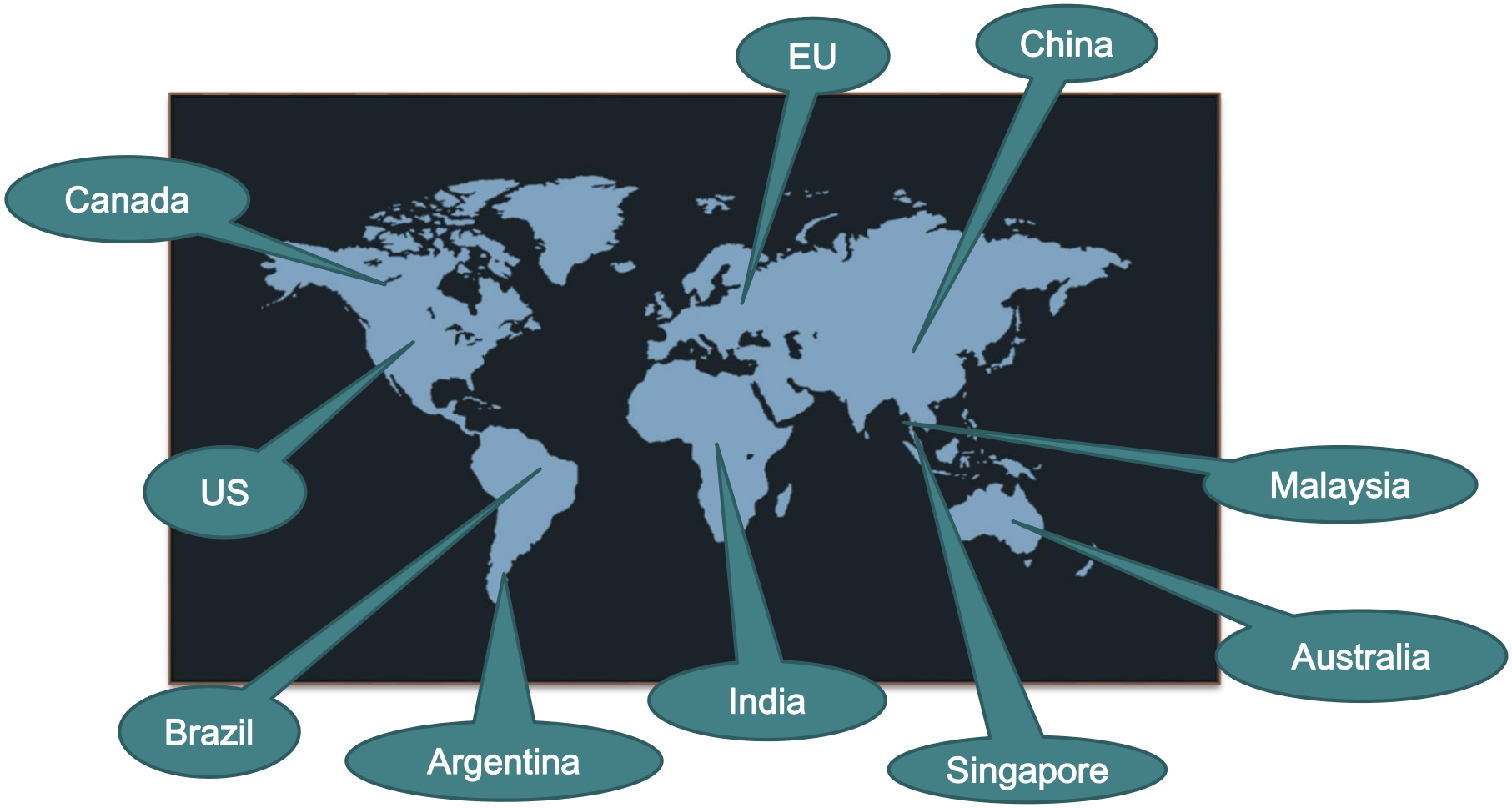


客戶
倉庫

藥品運銷管理

- 供應鏈複雜度
- 關鍵風險

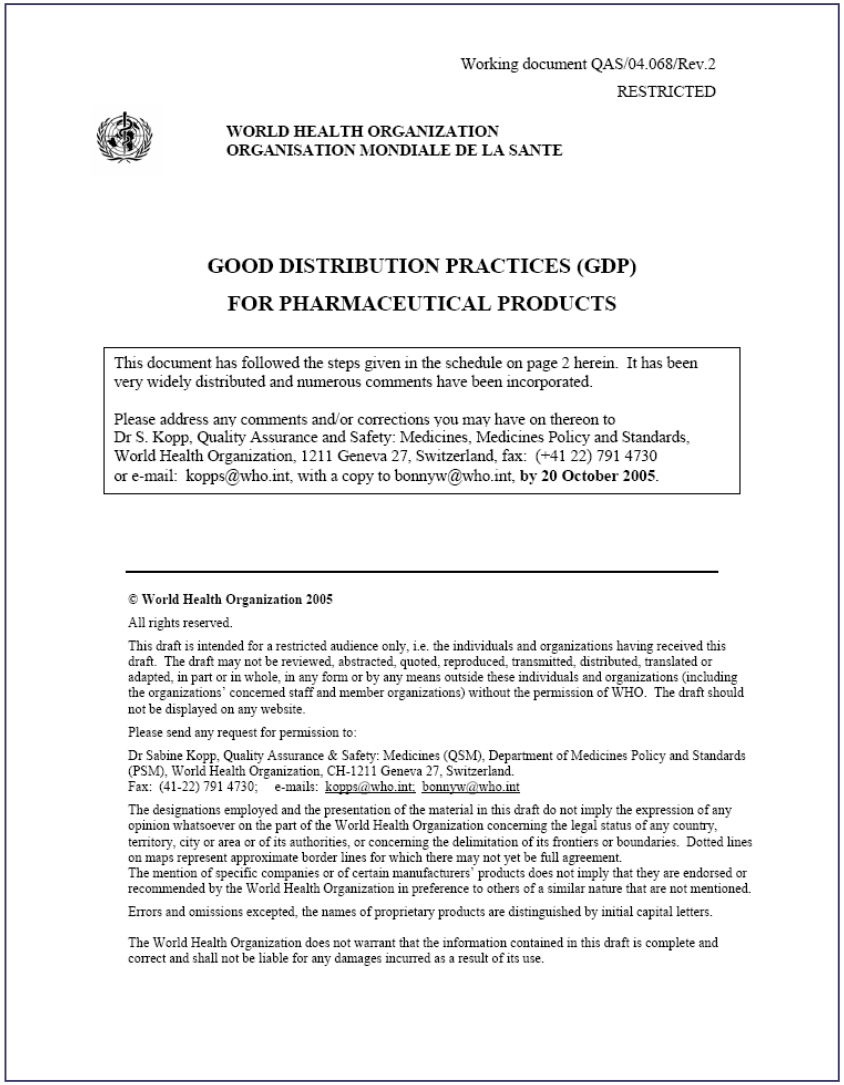
已建立藥品GDP相關制度之國家



WHO-1

項目	內容
名稱	GOOD DISTRIBUTION PRACTICES (GDP) FOR PHARMACEUTICAL PRODUCTS (Draft)
時間	2004(revised 2005)
範圍	Pharmaceutical products

World Health Organization



Working document QAS/04.068/Rev.2
RESTRICTED

WORLD HEALTH ORGANIZATION
ORGANISATION MONDIALE DE LA SANTE

GOOD DISTRIBUTION PRACTICES (GDP)
FOR PHARMACEUTICAL PRODUCTS

This document has followed the steps given in the schedule on page 2 herein. It has been very widely distributed and numerous comments have been incorporated.

Please address any comments and/or corrections you may have on thereon to Dr S. Kopp, Quality Assurance and Safety: Medicines, Medicines Policy and Standards, World Health Organization, 1211 Geneva 27, Switzerland, fax: (+41 22) 791 4730 or e-mail: kopps@who.int, with a copy to bonnyw@who.int, **by 20 October 2005.**

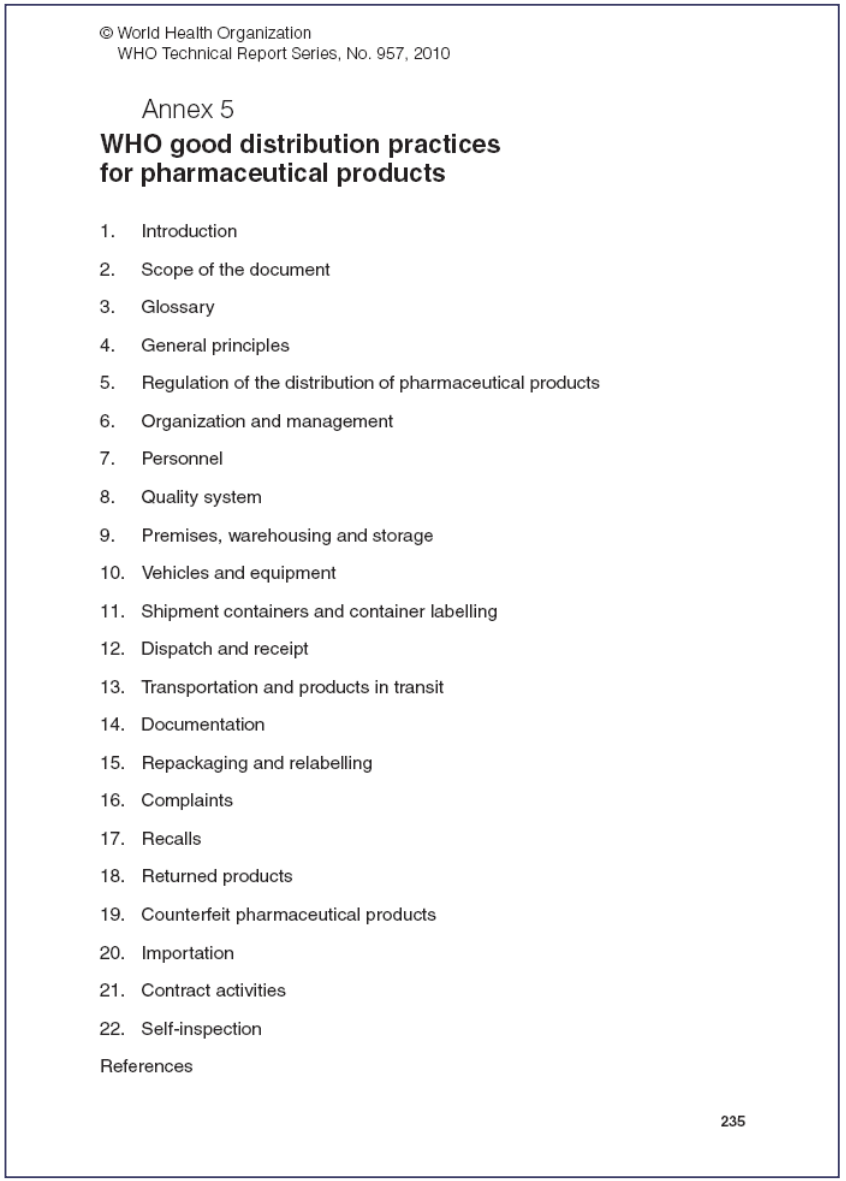
Download： http://www.who.int/medicines/services/expertcommittees/pharmprep/QAS_068Rev2_GDPdraft.pdf

WHO-2

- 1. Introduction
- 2. Scope of the document
- 3. Glossary
- 4. Organization and management
- 5. Personnel
- 6. Quality management
- 7. Premises, warehousing and storage
- 8. Vehicles and equipment
- 9. Containers and container labelling
- 10. Dispatch
- 11. Transportation and products in transit
- 12. Documentation
- 13. Repackaging and relabelling
- 14. Complaints
- 15. Recalls
- 16. Rejected and returned products
- 17. Counterfeit pharmaceutical products
- 18. Importation
- 19. Contract activities
- 20. Self-inspection
- 21. Bibliography

WHO-3

- **WHO Technical Report Series, No. 957 (2010)**
  - **Annex5**
    - **WHO- good distribution practices for pharmaceutical products**



WHO Technical Report Series, No. 957, 2010

Annex 5

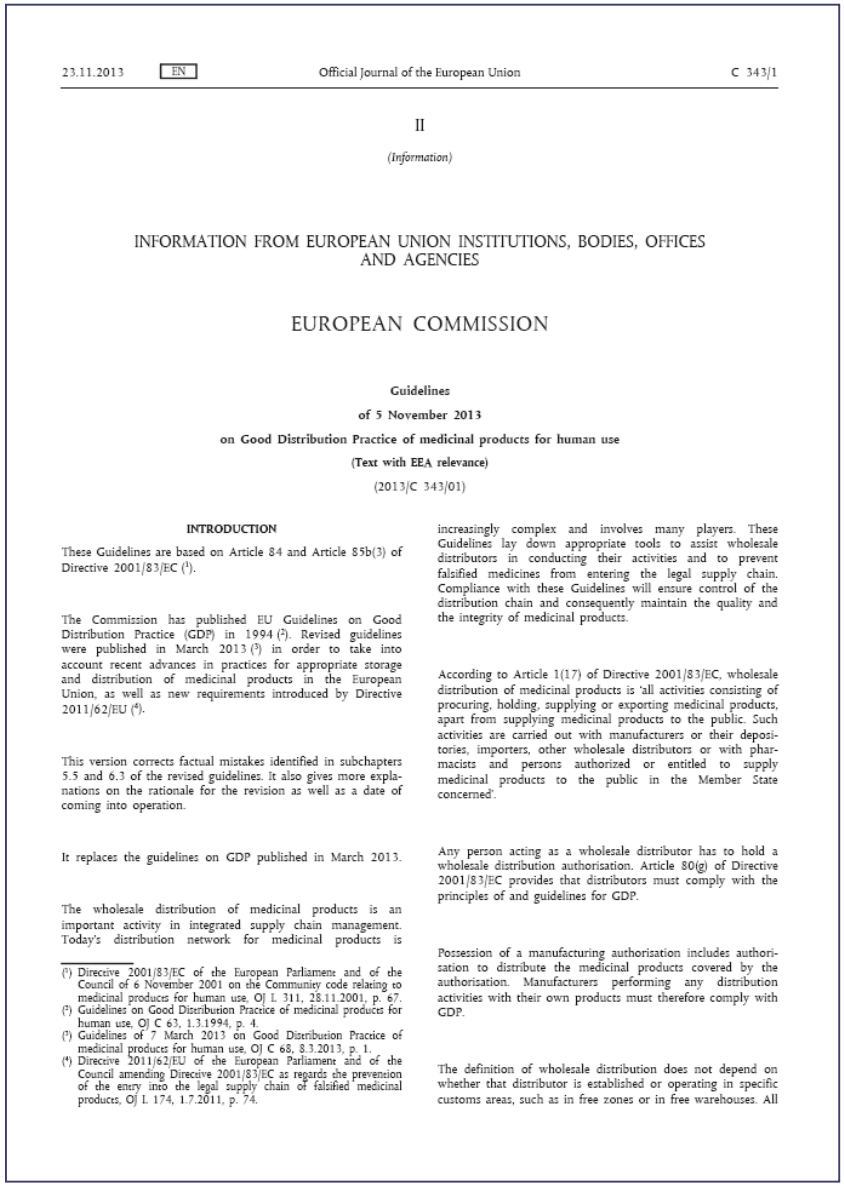
WHO good distribution practices for pharmaceutical products

Download：
http://www.who.int/medicines/areas/quality_safety/quality_assurance/GoodDistributionPracticesTRS957Annex5.pdf

EU-1

項目	內容
名稱	Good Distribution Practice of medicinal products for human use
時間	2011(revised 2013)
範圍	Medicinal products for human use

European Commission



23.11.2013 EN Official Journal of the European Union C 343/1

II

(Information)

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

Guidelines

of 5 November 2013

on Good Distribution Practice of medicinal products for human use

(Text with EEA relevance)

(2013/C 343/01)

INTRODUCTION

These Guidelines are based on Article 84 and Article 85b(3) of Directive 2001/83/EC [1].

The Commission has published EU Guidelines on Good Distribution Practice (GDP) in 1994 [2]. Revised guidelines were published in March 2013 [3] in order to take into account recent advances in practices for appropriate storage and distribution of medicinal products in the European Union, as well as new requirements introduced by Directive 2011/62/EU [4].

This version corrects factual mistakes identified in subchapters 5.5 and 6.3 of the revised guidelines. It also gives more explanations on the rationale for the revision as well as a date of coming into operation.

It replaces the guidelines on GDP published in March 2013.

The wholesale distribution of medicinal products is an important activity in integrated supply chain management. Today's distribution network for medicinal products is increasingly complex and involves many players. These Guidelines lay down appropriate tools to assist wholesale distributors in conducting their activities and to prevent falsified medicines from entering the legal supply chain. Compliance with these Guidelines will ensure control of the distribution chain and consequently maintain the quality and the integrity of medicinal products.

According to Article 1(17) of Directive 2001/83/EC, wholesale distribution of medicinal products is 'all activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public. Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorized or entitled to supply medicinal products to the public in the Member State concerned'.

Any person acting as a wholesale distributor has to hold a wholesale distribution authorisation. Article 80(g) of Directive 2001/83/EC provides that distributors must comply with the principles of and guidelines for GDP.

Possession of a manufacturing authorisation includes authorisation to distribute the medicinal products covered by the authorisation. Manufacturers performing any distribution activities with their own products must therefore comply with GDP.

The definition of wholesale distribution does not depend on whether that distributor is established or operating in specific customs areas, such as in free zones or in free warehouses. All

[1] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67.
[2] Guidelines on Good Distribution Practice of medicinal products for human use, OJ C 63, 1.3.1994, p. 4.
[3] Guidelines of 7 March 2013 on Good Distribution Practice of medicinal products for human use, OJ C 68, 8.3.2013, p. 1.
[4] Directive 2011/62/EU of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of falsified medicinal products, OJ L 174, 1.7.2011, p. 74.

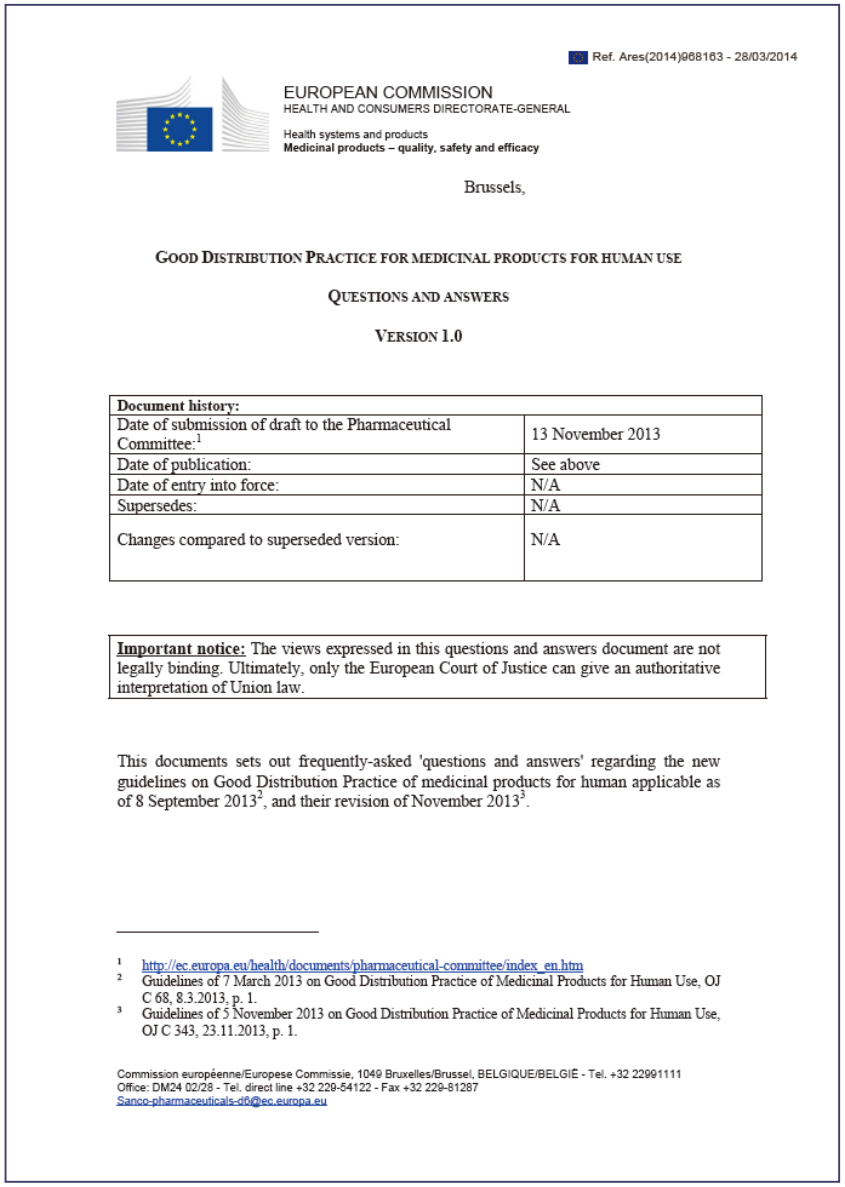
Download： http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:343:0001:0014:EN:PDF

EU-2

- CHAPTER 1 — QUALITY MANAGEMENT
- CHAPTER 2 — PERSONNEL
- CHAPTER 3 — PREMISES AND EQUIPMENT
- CHAPTER 4 — DOCUMENTATION
- CHAPTER 5 — OPERATIONS
- CHAPTER 6 — COMPLAINTS, RETURNS, SUSPECTED FALSIFIED MEDICINAL PRODUCTS AND MEDICINAL PRODUCT RECALLS
- CHAPTER 7 — OUTSOURCED ACTIVITIES
- CHAPTER 8 — SELF-INSPECTIONS
- CHAPTER 9 — TRANSPORTATION
- CHAPTER 10 — SPECIFIC PROVISIONS FOR BROKERS
- CHAPTER 11 — FINAL PROVISIONS

EU-3

- **GOOD DISTRIBUTION PRACTICE FOR MEDICINAL PRODUCTS FOR HUMAN USE QUESTIONS AND ANSWERS V.1(2013)**
  - Ch2- PERSONNEL
  - Ch3- PREMISES AND EQUIPMENT,
  - Ch5- OPERATIONS
  - Ch6- COMPLAINTS, RETURNS, SUSPECTED FALSIFIED MEDICINAL PRODUCTS AND MEDICINAL PRODUCT RECALLS
  - Ch9- TRANSPORTATION



Ref. Ares(2014)968163 - 28/03/2014

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
Medicinal products – quality, safety and efficacy

Brussels,

GOOD DISTRIBUTION PRACTICE FOR MEDICINAL PRODUCTS FOR HUMAN USE

QUESTIONS AND ANSWERS

VERSION 1.0

Document history:	
Date of submission of draft to the Pharmaceutical Committee:[1]	13 November 2013
Date of publication:	See above
Date of entry into force:	N/A
Supersedes:	N/A
Changes compared to superseded version:	N/A

Important notice: The views expressed in this questions and answers document are not legally binding. Ultimately, only the European Court of Justice can give an authoritative interpretation of Union law.

This documents sets out frequently-asked 'questions and answers' regarding the new guidelines on Good Distribution Practice of medicinal products for human applicable as of 8 September 2013[2], and their revision of November 2013[3].

1 http://ec.europa.eu/health/documents/pharmaceutical-committee/index_en.htm
2 Guidelines of 7 March 2013 on Good Distribution Practice of Medicinal Products for Human Use, OJ C 68, 8.3.2013, p. 1.
3 Guidelines of 5 November 2013 on Good Distribution Practice of Medicinal Products for Human Use, OJ C 343, 23.11.2013, p. 1.

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111
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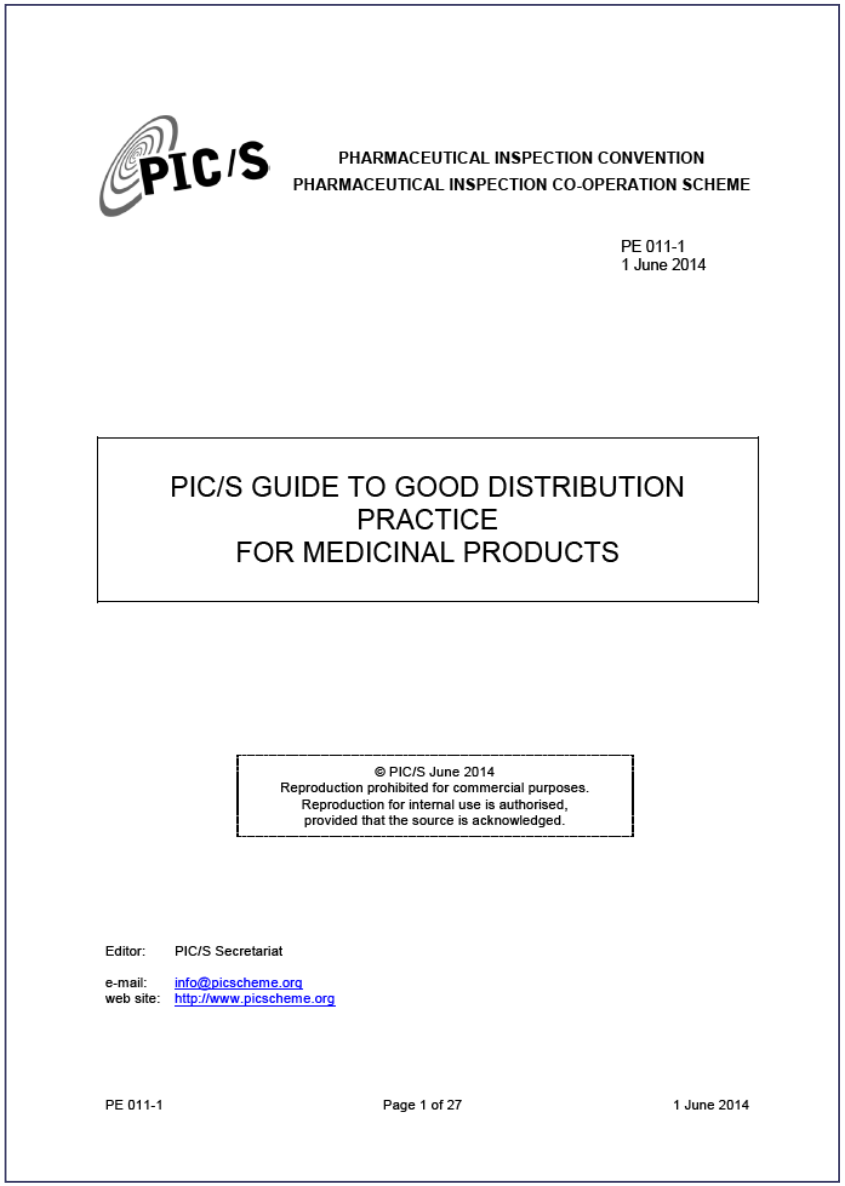
Sanco-pharmaceuticals-d6@ec.europa.eu

Download： http://ec.europa.eu/health/files/gdp/2014-04_qas_.pdf

PIC/S-1

項目	內容
名稱	PIC/S GUIDE TO GOOD DISTRIBUTION PRACTICE FOR MEDICINAL PRODUCTS
時間	2014
範圍	Medicinal products



PIC/S

PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PE 011-1
1 June 2014

PIC/S GUIDE TO GOOD DISTRIBUTION PRACTICE FOR MEDICINAL PRODUCTS

Editor: PIC/S Secretariat

e-mail: info@picscheme.org
web site: http://www.picscheme.org

Download：
http://www.picscheme.org/publication.php?download&file=cGUtMDExLTEtcGljcy1nZHAtZ3VpZGUucGRm

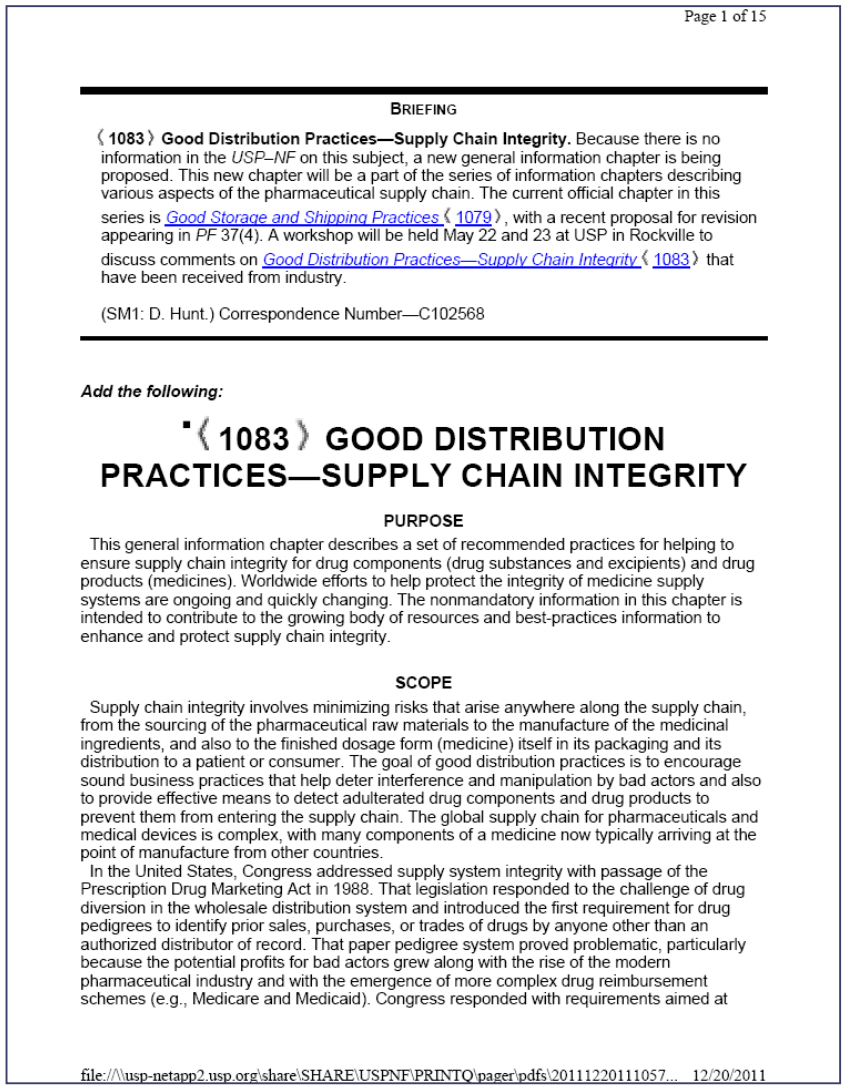
PIC/S-2

- CH1：QUALITY MANAGEMENT
- CH2： PERSONNEL
- CH3： PREMISES AND EQUIPMENT
- CH4： DOCUMENTATION
- CH5： OPERATIONS
- CH6： COMPLAINTS, RETURNS, SUSPECTED FALSIFIED MEDICINAL PRODUCTS AND MEDICINAL PRODUCT RECALLS
- CH7： OUTSOURCED ACTIVITIES
- CH8： SELF-INSPECTIONS
- CH9： TRANSPORTATION

US-1

項目	內容
名稱	GOOD DISTRIBUTION PRACTICES—SUPPLY CHAIN INTEGRITY
時間	2011
範疇	•Drugs •Medical Devices

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health



Page 1 of 15

BRIEFING

《1083》**Good Distribution Practices—Supply Chain Integrity.** Because there is no information in the *USP–NF* on this subject, a new general information chapter is being proposed. This new chapter will be a part of the series of information chapters describing various aspects of the pharmaceutical supply chain. The current official chapter in this series is *Good Storage and Shipping Practices* 《1079》, with a recent proposal for revision appearing in *PF* 37(4). A workshop will be held May 22 and 23 at USP in Rockville to discuss comments on *Good Distribution Practices—Supply Chain Integrity* 《1083》 that have been received from industry.

(SM1: D. Hunt.) Correspondence Number—C102568

Add the following:

▪《1083》GOOD DISTRIBUTION PRACTICES—SUPPLY CHAIN INTEGRITY

PURPOSE

This general information chapter describes a set of recommended practices for helping to ensure supply chain integrity for drug components (drug substances and excipients) and drug products (medicines). Worldwide efforts to help protect the integrity of medicine supply systems are ongoing and quickly changing. The nonmandatory information in this chapter is intended to contribute to the growing body of resources and best-practices information to enhance and protect supply chain integrity.

SCOPE

Supply chain integrity involves minimizing risks that arise anywhere along the supply chain, from the sourcing of the pharmaceutical raw materials to the manufacture of the medicinal ingredients, and also to the finished dosage form (medicine) itself in its packaging and its distribution to a patient or consumer. The goal of good distribution practices is to encourage sound business practices that help deter interference and manipulation by bad actors and also to provide effective means to detect adulterated drug components and drug products to prevent them from entering the supply chain. The global supply chain for pharmaceuticals and medical devices is complex, with many components of a medicine now typically arriving at the point of manufacture from other countries.

In the United States, Congress addressed supply system integrity with passage of the Prescription Drug Marketing Act in 1988. That legislation responded to the challenge of drug diversion in the wholesale distribution system and introduced the first requirement for drug pedigrees to identify prior sales, purchases, or trades of drugs by anyone other than an authorized distributor of record. That paper pedigree system proved problematic, particularly because the potential profits for bad actors grew along with the rise of the modern pharmaceutical industry and with the emergence of more complex drug reimbursement schemes (e.g., Medicare and Medicaid). Congress responded with requirements aimed at

file://\\usp-netapp2.usp.org\share\SHARE\USPNF\PRINTQ\pager\pdfs\20111220111057... 12/20/2011

Download： http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/revisions/c1083.pdf

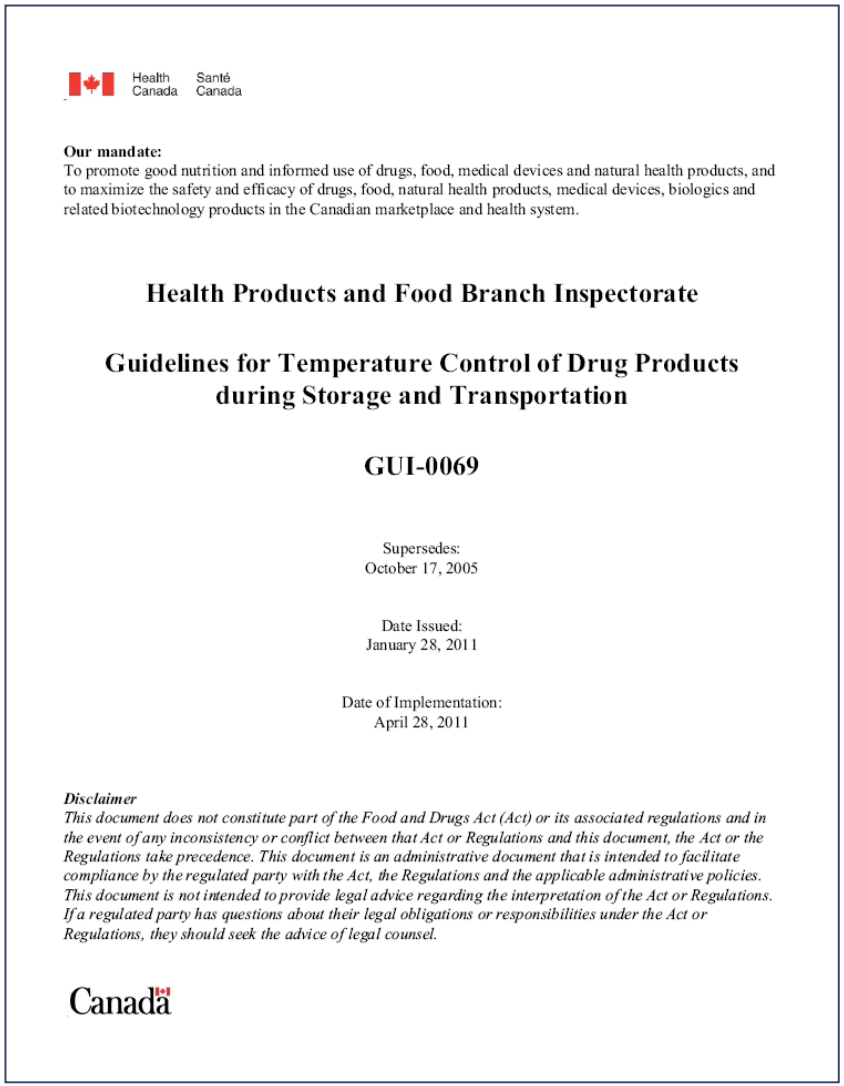
US-2

- **DEFINITIONS**
  - Importation
  - Supply Chain Risk Management
  - Development of Effective Supplier Partnerships
  - Building a Supply Chain Quality System
- **COUNTERFEIT DRUGS AND MEDICAL DEVICES**
  - Definitions of Counterfeit and Substandard Drugs
  - Types of Counterfeit Drugs
  - Medical Consequences of Counterfeit Drugs
  - Distribution and Extent of Counterfeit Drugs and Devices
- **BEST PRACTICES TO COMBAT COUNTERFEIT DRUGS AND MEDICAL DEVICES**
  - Packaging Technologies
  - Establishment of Drug Pedigrees
  - Application of Machine-Readable Data Carriers to Drug Products
  - Repackaging Guidance, Information Retention, and Security
  - International Standards and Global Approaches to Establishing Drug Pedigrees
  - Combating Illegal Internet Pharmacies
  - Best Anticounterfeiting Practices
- **DIVERSION AND THEFT**

Canada-1

項目	內容
名稱	Guidelines for Temperature Control of Drug Products during Storage and Transportation
時間	2005 (revised 2011)
範圍	Drug Products

Health Canada Santé Canada



Health Canada Santé Canada

Our mandate:
To promote good nutrition and informed use of drugs, food, medical devices and natural health products, and to maximize the safety and efficacy of drugs, food, natural health products, medical devices, biologics and related biotechnology products in the Canadian marketplace and health system.

Health Products and Food Branch Inspectorate

Guidelines for Temperature Control of Drug Products during Storage and Transportation

GUI-0069

Supersedes:
October 17, 2005

Date Issued:
January 28, 2011

Date of Implementation:
April 28, 2011

Disclaimer
This document does not constitute part of the Food and Drugs Act (Act) or its associated regulations and in the event of any inconsistency or conflict between that Act or Regulations and this document, the Act or the Regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the Regulations and the applicable administrative policies. This document is not intended to provide legal advice regarding the interpretation of the Act or Regulations. If a regulated party has questions about their legal obligations or responsibilities under the Act or Regulations, they should seek the advice of legal counsel.

Canada

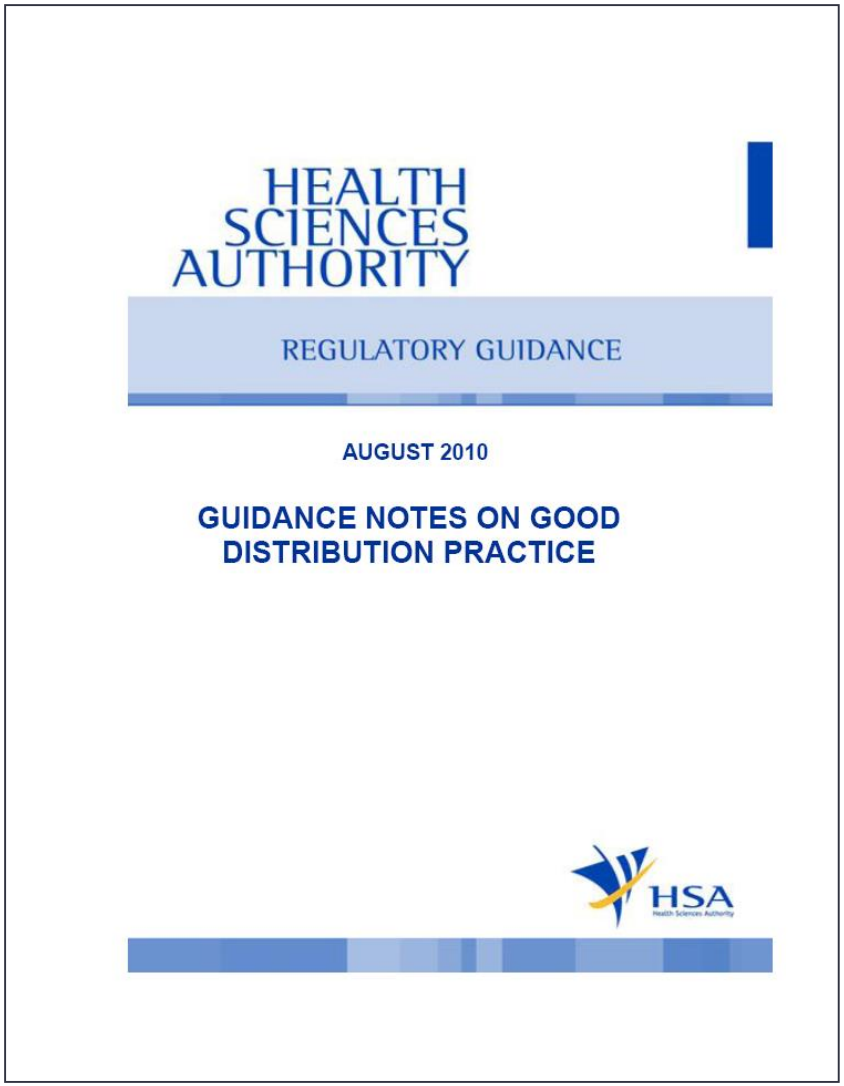
Download： http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/compli-conform/gmp-bpf/docs/GUI-0069-eng.pdf

Canada-2

- Introduction
- Scope
- Interpretation
  - Warehousing and Storage
  - Product Transportation and Products in Transit
  - Containers and Container Labelling
  - Receiving
  - Documentation

Singapore-1

項目	內容
名稱	GUIDANCE NOTES ON GOOD DISTRIBUTION PRACTICE
時間	2010
範圍	•Starting materials •Medicinal products



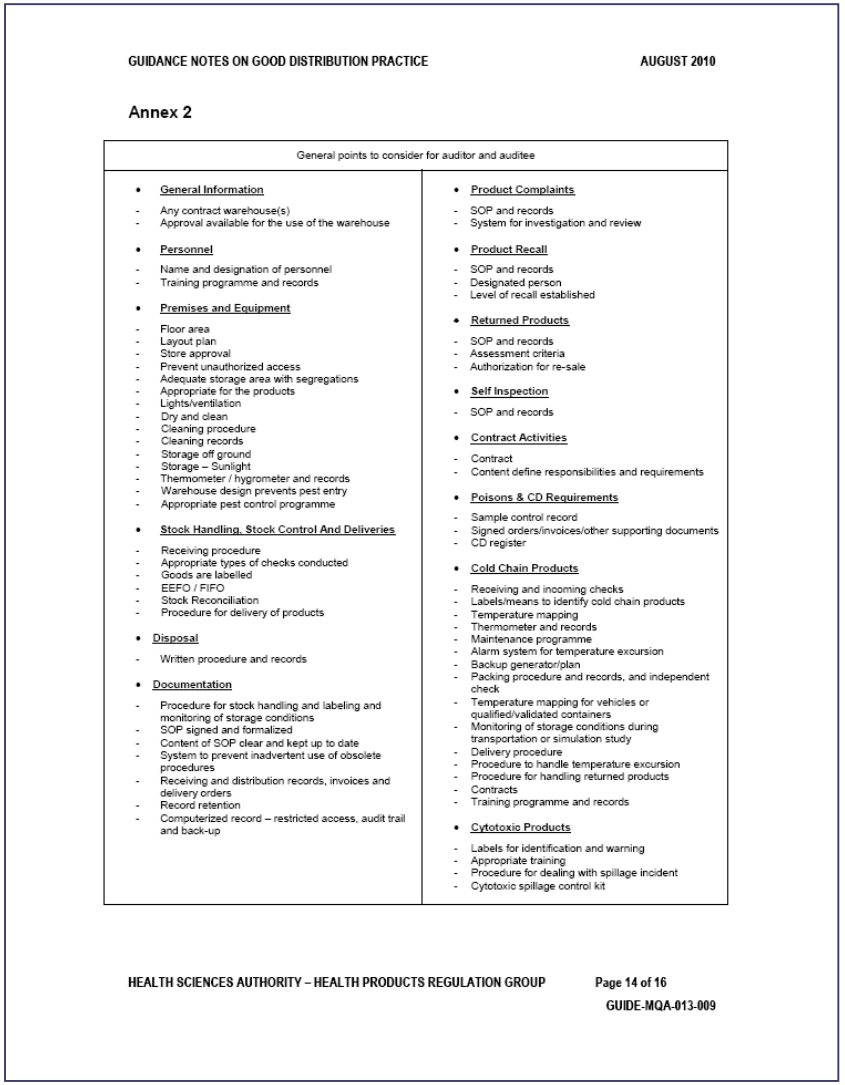
Download： http://www.hsa.gov.sg/content/dam/HSA/HPRG/Manufacturing_Importation_Distribution/Guidelines-on-Good-Manufacturing-Practice-Standard-and-Good-Distribution-Practice-Standard/GUIDE-MQA-013-009.pdf

Singapore-2

- 1 PERSONNEL
- 2 PREMISES AND EQUIPMENT
- 3 STOCK HANDLING, STOCK CONTROL AND DELIVERIES
- 4 DISPOSAL OF PRODUCTS
- 5 DOCUMENTATION
- 6 PRODUCT COMPLAINTS
- 7 PRODUCT RECALL
- 8 RETURNED PRODUCTS
- 9 COUNTERFEIT PRODUCTS
- 10 SELF-INSPECTION
- 11 CONTRACT ACTIVITIES
- 12 HANDLING OF ACTIVE PHARMACEUTICAL INGREDIENT OR INTERMEDIATES

Singapore-3

- Annex1
  - COLD CHAIN PRODUCTS
- Annex2
  - General points to consider for auditor and auditee



GUIDANCE NOTES ON GOOD DISTRIBUTION PRACTICE AUGUST 2010

Annex 2

General points to consider for auditor and auditee

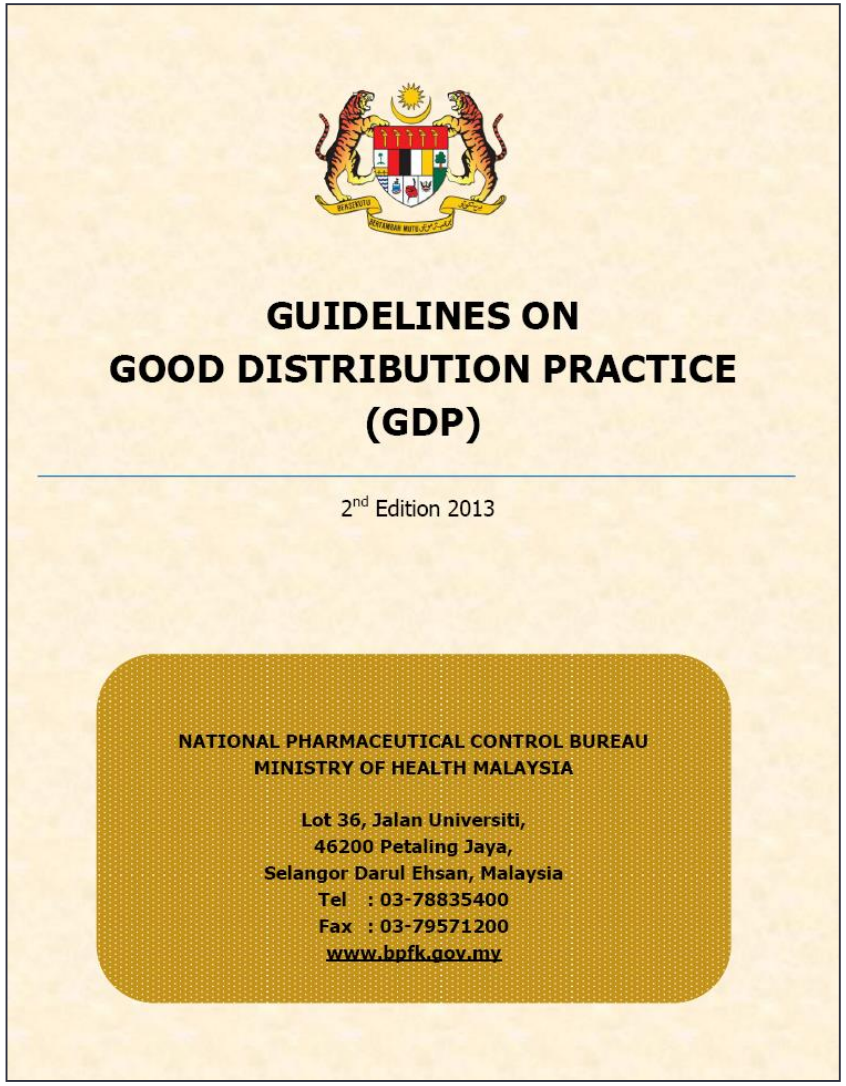
- **General Information**
  - Any contract warehouse(s)
  - Approval available for the use of the warehouse
- **Personnel**
  - Name and designation of personnel
  - Training programme and records
- **Premises and Equipment**
  - Floor area
  - Layout plan
  - Store approval
  - Prevent unauthorized access
  - Adequate storage area with segregations
  - Appropriate for the products
  - Lights/ventilation
  - Dry and clean
  - Cleaning procedure
  - Cleaning records
  - Storage off ground
  - Storage – Sunlight
  - Thermometer / hygrometer and records
  - Warehouse design prevents pest entry
  - Appropriate pest control programme
- **Stock Handling, Stock Control And Deliveries**
  - Receiving procedure
  - Appropriate types of checks conducted
  - Goods are labelled
  - EEFO / FIFO
  - Stock Reconciliation
  - Procedure for delivery of products
- **Disposal**
  - Written procedure and records
- **Documentation**
  - Procedure for stock handling and labeling and monitoring of storage conditions
  - SOP signed and formalized
  - Content of SOP clear and kept up to date
  - System to prevent inadvertent use of obsolete procedures
  - Receiving and distribution records, invoices and delivery orders
  - Record retention
  - Computerized record – restricted access, audit trail and back-up
- **Product Complaints**
  - SOP and records
  - System for investigation and review
- **Product Recall**
  - SOP and records
  - Designated person
  - Level of recall established
- **Returned Products**
  - SOP and records
  - Assessment criteria
  - Authorization for re-sale
- **Self Inspection**
  - SOP and records
- **Contract Activities**
  - Contract
  - Content define responsibilities and requirements
- **Poisons & CD Requirements**
  - Sample control record
  - Signed orders/invoices/other supporting documents
  - CD register
- **Cold Chain Products**
  - Receiving and incoming checks
  - Labels/means to identify cold chain products
  - Temperature mapping
  - Thermometer and records
  - Maintenance programme
  - Alarm system for temperature excursion
  - Backup generator/plan
  - Packing procedure and records, and independent check
  - Temperature mapping for vehicles or qualified/validated containers
  - Monitoring of storage conditions during transportation or simulation study
  - Delivery procedure
  - Procedure to handle temperature excursion
  - Procedure for handling returned products
  - Contracts
  - Training programme and records
- **Cytotoxic Products**
  - Labels for identification and warning
  - Appropriate training
  - Procedure for dealing with spillage incident
  - Cytotoxic spillage control kit

HEALTH SCIENCES AUTHORITY – HEALTH PRODUCTS REGULATION GROUP Page 14 of 16

GUIDE-MQA-013-009

Malaysia-1

項目	內容
名稱	Guidelines on Good Distribution Practice
時間	2011 (revised 2013)
範圍	•Products •Cosmetics • Materials



GUIDELINES ON
GOOD DISTRIBUTION PRACTICE
(GDP)

2nd Edition 2013

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Malaysia-2

- CHAPTER 1: QUALITY MANAGEMENT
- CHAPTER 2: PERSONNEL
- CHAPTER 3: PREMISES AND FACILITIES
- CHAPTER 4: STOCK HANDLING AND STOCK CONTROL
- CHAPTER 5: DISPOSAL OF MATERIALS / PRODUCTS / COSMETICS
- CHAPTER 6: DOCUMENTATION
- CHAPTER 7: VEHICLES AND EQUIPMENT
- CHAPTER 8: TRANSPORTATION AND GOODS IN TRANSIT
- CHAPTER 9: PRODUCT / COSMETIC COMPLAINTS
- CHAPTER 10: PRODUCT / COSMETIC RECALL
- CHAPTER 11: SELF INSPECTION
- CHAPTER 12: COUNTERFEIT MATERIALS/ PRODUCTS/ COSMETICS
- CHAPTER 13: CONTRACT ACTIVITIES
- CHAPTER 14: LEGAL DOCUMENTS
- CHAPTER 15: MANAGEMENT OF COLD CHAIN PRODUCTS/ MATERIALS

	WHO	EU	PIC/S	US	Canada	Singapore	Malaysia
Personnel	7	2	2			1	2
Quality management	8	1	1	1			1
Premises, warehousing and storage	9	3	3		3.1	2	3
Vehicles and equipment	10	9	9		3.2		7
Containers and container labelling	11	9	9		3.3	3	3
Dispatch	12	5	5		3.4	3	4
Transportation and products in transit	13	9	9		3.2	3	8
Documentation	14	4	4		3.5	5	6
Repackaging and relabelling	15	5	5	3			6
Complaints	16	6	6			6	9
Recalls	17	6	6			7	10
Rejected and returned products	18	6	6			8	4
Counterfeit pharmaceutical products	19	6	6	2		9	12
Importation	20	5	5	1			14
Contract activities	21	7	7			11	13
Self-inspection	22	8	8			10	11
Cold chain management						Annex	15
Disposal		5	5			4	5

國際藥品GDP常見缺失

國際藥品GDP常見缺失

- 文件繕寫
- 指定負責人員
- 溫度管控
- 自我稽核
- 紀錄保存
- 存貨管理

文件繕寫

- SOP與實際作業現況不符，文件未持續更新
- 部分文件過於冗長，未善用流程圖
- SOP未涵蓋完整作業細節，需要再索引至其他文件，現場作業人員無法取得

【PIC/S GDP】4.2.8 Attention should be paid to using valid and approved procedures. Documents should have unambiguous content; title, nature and purpose should be clearly stated. Documents should be reviewed regularly and kept up to date.

【PIC/S GDP】4.2.7 Each employee should have ready access to all necessary documentation for the tasks executed.

指定負責人員(RP)

- 指定負責人員未能建立有效回收系統
- 指定負責人員未對回收系統進行測試
- 指定負責人員缺乏對委外作業的監督

【PIC/S GDP】2.3.5 The responsibilities of the designated responsible person(s) include but are not limited to: iv) coordinating and promptly performing any recall operations for medicinal products; vii) approving any subcontracted activities which may impact on GDP

溫度管控-1

- Mapping執行之有效性，監控點須有足夠證據證實
- 警報系統時常作響，使作業人員習慣性忽略，確保警報系統有效運作且作響頻率不可太高

【PIC/S GDP】3.3.2 An initial temperature mapping exercise should be carried out on the storage area before use, under representative conditions. Temperature monitoring equipment should be located according to the results of the mapping exercise, ensuring that monitoring devices are positioned in the areas that experience the extremes of fluctuations.3
【PIC/S GDP】3.4.3 Appropriate alarm systems should be in place to provide alerts when there are excursions from predefined storage conditions. Alarm levels should be appropriately set and alarms should be regularly tested to ensure adequate functionality.

溫度管控-2

- 製造廠宣稱距離短暫而忽略cold-chain產品溫度儲存要求
- 需要特殊儲存條件之產品，於供應鏈中無適當的儲存環境

【PIC/S GDP】9.2.1 The required storage conditions for medicinal products should be maintained during transportation within the defined limits as described on the outer packaging and/or relevant packaging information.
【PIC/S GDP】9.2.3 It is the responsibility of the wholesale distributor to ensure that vehicles and equipment used to distribute, store or handle medicinal products are suitable for their use and appropriately equipped to prevent exposure of the products to conditions that could affect their quality and packaging integrity.
【PIC/S GDP】9.2.10 Provision should be made to minimise the duration of temporary storage while awaiting the next stage of the transportation route.

溫度管控-3

- 裝存箱櫃標示不明，無法確認外包裝拆除狀態
- 冷鏈產品之退回，無取得足夠的產品儲存資訊(依據退回的對象不同，提供的資訊應不同)
- 空運經過不只一個國家，標示須被每隔國家看懂(圖示)

【PIC/S GDP】9.3.3 Containers should bear labels providing sufficient information on handling and storage requirements and precautions to ensure that the products are properly handled and secured at all times. The containers should enable identification of the contents of the containers and the source.

【PIC/S GDP】6.3.3 for medicinal products requiring specific temperature storage conditions such as low temperature, returns to saleable stock can only be made if there is documented evidence that the product has been stored under the authorised storage conditions throughout the entire time.

自我稽核

- 自我稽核之有效性(未涵蓋GDP關鍵區域)
- 自我稽核之後續矯正預防措施及其有效性

【PIC/S GDP】8.2.1 A self-inspection programme should be implemented covering all aspects of GDP and compliance with the regulations, guidelines and procedures within a defined time frame. Self-inspections may be divided into several individual self-inspections of limited scope.

【PIC/S GDP】8.2.3 All self-inspections should be recorded. Reports should contain all the observations made during the inspection. A copy of the report should be provided to the management and other relevant persons. In the event that irregularities and/or deficiencies are observed, their cause should be determined and the corrective and preventive actions (CAPA) should be documented and followed up.

紀錄保存

- 與藥品運銷相關紀錄應保存五年以上
- 未保存供應商評估紀錄(評估其適當性、能力、實質檢核(Due Diligence))

【PIC/S GDP】4.2.6 Documents should be retained for the period stated in national legislation but at least 5 years.
【PIC/S GDP】5.2.3Appropriate qualification and approval of suppliers should be performed prior to procurement of any medicinal products. This should be controlled by a procedure and the results documented and periodically rechecked using a risk based approach.
【PIC/S GDP】5.2.4 When entering into a new contract with new suppliers the wholesale distributor should carry out 'due diligence' checks in order to assess the suitability, competence and reliability of the other party.

存貨管理

- 使用先進先出法，而非先到期先出
- 退回品未有效評估

【PIC/S GDP】5.5.4 Stock should be rotated according to the first expiry, first out (FEFO) principle. Exceptions should be documented.

【PIC/S GDP】6.3.1 Returned products must be handled according to a written, risk based process taking into account the product concerned, any specific storage requirements and the time elapsed since the medicinal product was originally dispatched. Returns should be conducted in accordance with national law, if relevant, and contractual arrangements between the parties. A record/ list of returned goods must be maintained.

結論

- 善用文件管理
- 藥品GDP人員訓練
- 藥品儲存及配送過程之溫度管控
- 藥品運銷紀錄追溯(逆物流管理)

Thank you for your attention !