Management of outsourced warehousing and transportation for medicinal products

藥品委外倉儲及運輸管理

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Introduction

- Aim of presentation today is to describe how Company (Contract Giver 委託者) manage outsourced warehousing and transportation activities based on PIC/S Guide to Good Distribution Practice for Medicinal Products, Chapter 7 Outsourced Activities (委外作業)

- Important to know that Contract Giver is still ultimately responsible for the compliance of the outsourced GDP activities to ensure product quality and patient safety
  - i.e. compliance to requirements as described in the GDP Guidelines adopted by country regulator

很重要必須知道的是 委託者仍應對所有外包GDP作業的遵循 負完全的責任(全權負責)以確保產品的品質和病人的安全

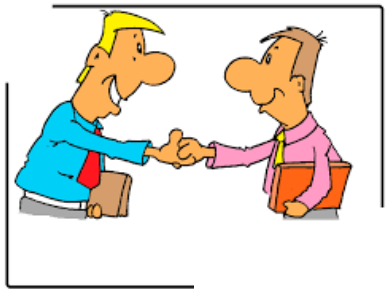
Agenda

Today presentation key points for management of outsourced warehousing and transportation activities are

- Evaluation and qualification of warehouse/transport service provider (Contract Acceptor, typically Distributor or Transport Company)
- Set up of Quality Agreement between Contract Giver and Contract Acceptor
- Management of subcontract warehousing and transportation activities

委外管理之重點:

- 委外倉儲/運輸之受託商評估、稽核
- 委受託雙方品質協議書制訂
- 委外倉儲/運輸再委託第三方之管理



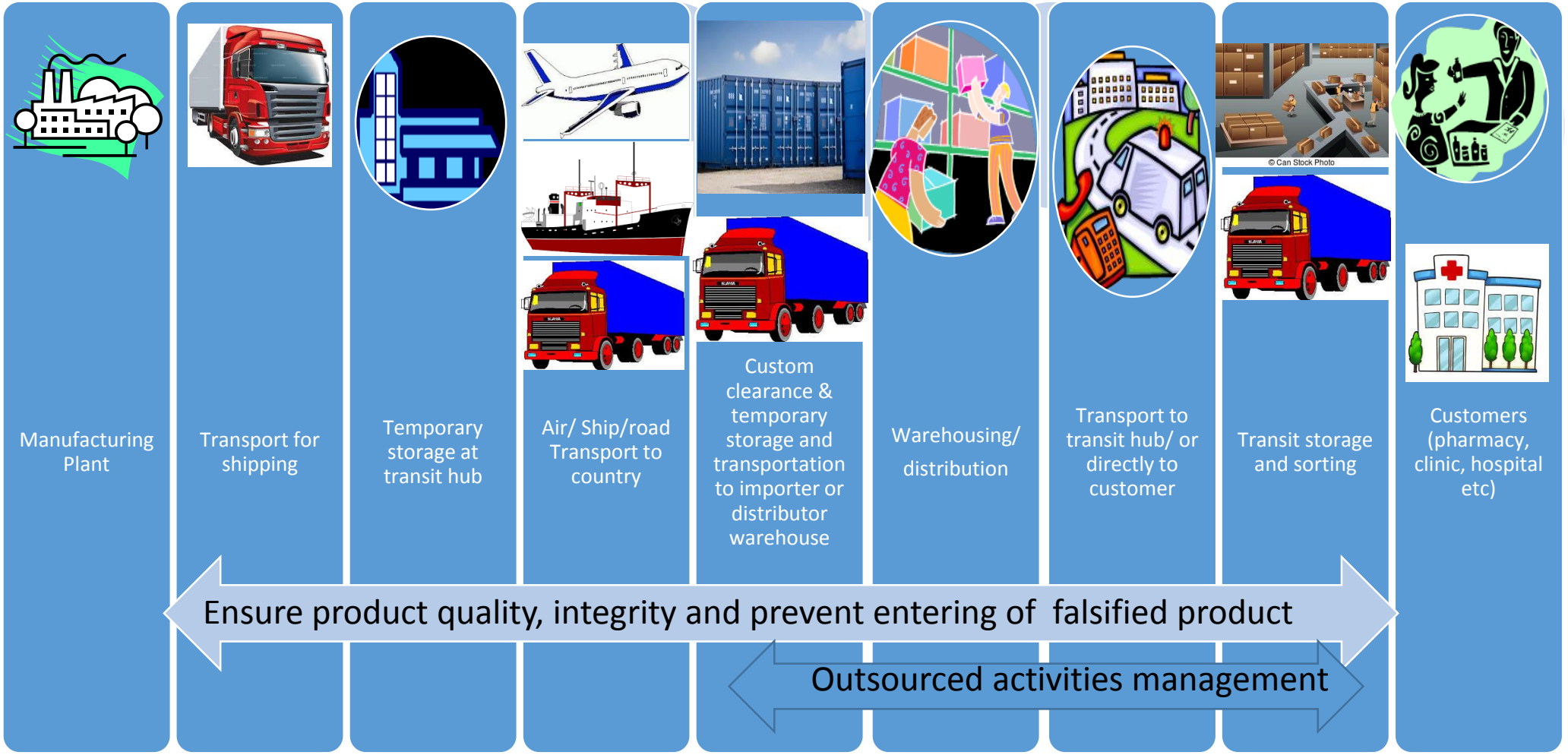
PIC/S Guide to Good Distribution Practice for Medicinal Products PE011-1 (1 June 2014)

Purpose of Good Distribution Practice Guidelines –規範制定的目的

- 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.

- 藥品的批發運銷是整合供應鏈管理中重要的活動。現今的藥品運銷網絡日益複雜且包含許多參與者。本規範制定適當的工具以協助批發運銷商進行其活動，並預防偽、禁藥流入合法供應鏈中。遵守本規範可確保運銷鏈的管控，進而維護藥品的品質與完整性。

Understand the Supply Chain map to identify the multiple players involved and the GDP control



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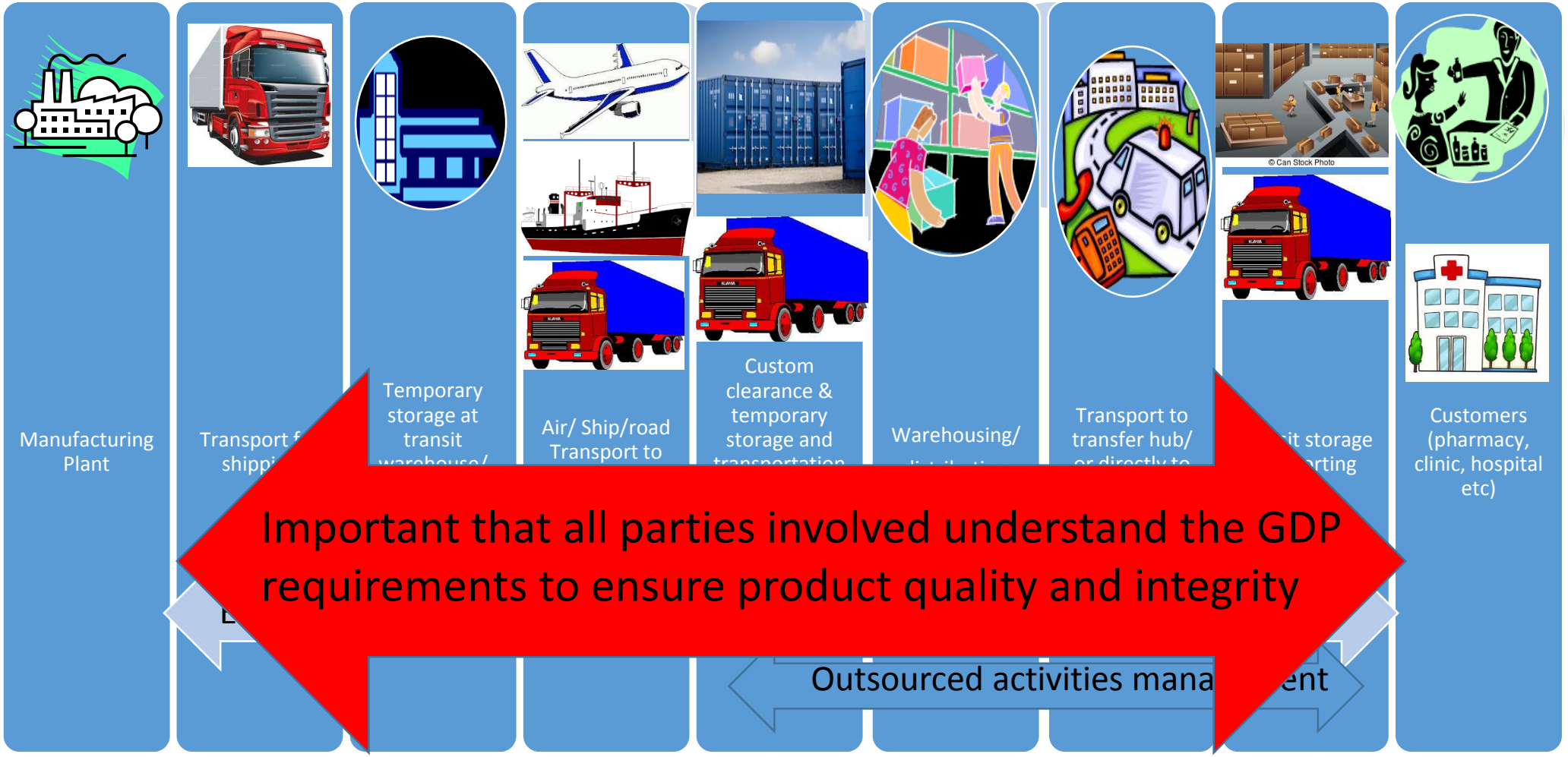


Some factors that could affect product quality and integrity

- Temperature 溫度
- Humidity 濕度
- Light 日光
- Damage破損
- Hygiene and cleanliness衛生, 清潔
- Security 安全
- Contamination 污染
- Mix up 混淆

Inappropriate management of product handling at any stage of supply chain could jeopardize product quality and integrity

PIC/S Guide to GDP-chapter 7 Outsourced Activities

7.1 Principle 原則

Any activity covered by the GDP Guide that is outsourced should be correctly defined, agreed and controlled in order to avoid misunderstandings which could affect the integrity of the product. There must be a written Contract between the Contract Giver and the Contract Acceptor which clearly establishes the duties of each party.

任何本規範所涵蓋之委外作業應清楚界定、同意且管制，以避免發生可能影響產品完整性之誤解。委託者與受託者之間須有書面合約，合約中清楚訂定雙方責任歸屬。

PIC/S Guide to GDP-chapter 7 Outsourced Activities

7.2 CONTRACT GIVER 委託者

7.2.1 The Contract Giver is responsible for the activities contracted out. 委託者負責將作業外包

7.2.2 The Contract Giver is responsible for assessing the competence of the Contract Acceptor to successfully carry out the work required and for ensuring by means of the contract and through audits that the principles and guidelines of GDP are followed. An audit of the Contract Acceptor should be performed before commencement of, and whenever there has been a change to, the outsourced activities. The requirement for audit and frequency should be defined based on risk depending on the nature of the outsourced activities. Audits should be permitted at any time.

委託者負責評估受託者確實履行要求之工作能力，確保本規範所闡述之藥品優良運銷規範的原則與指引受到遵循。委外作業開始前及有變更時，應進行受託者之稽核，稽核頻率應基於委外作業之風險予以規範，委託者應可隨時進行稽核

7.2.3 The Contract Giver should provide the Contract Acceptor with all the information necessary to carry out the contracted operations in accordance with the specific product requirements and any other relevant requirements.

委託者應提供受託者所有必要的資訊，以使其依照特定之產品要求及任何其他相關要求，正確履行約定的作業。

PIC/S Guide to GDP-chapter 7 Outsourced Activities

7.3 CONTRACT ACCEPTOR 受託者

7.3.1 The Contract Acceptor is responsible for the activities covered by GDP and delegated by the Contract Giver.

受託者應負責GDP 涵蓋範圍及委託者委派之活動。

7.3.2 The Contract Acceptor should have adequate premises and equipment, procedures, knowledge and experience, and competent personnel to carry out the work ordered by the Contract Giver.

受託者應有適當的作業場所與設備、程序、知識與經驗及勝任人員，以執行委託者所託付的工作。

7.3.3 The Contract Acceptor should not pass to a third party any of the work entrusted to him under the contract without the Contract Giver's prior evaluation and approval of the arrangements and an audit of the third party by the Contract Giver or the Contract Acceptor. Arrangements made between the Contract Acceptor and any third party should ensure that the wholesale distribution information is made available in the same way as between the original Contract Giver and Contract Acceptor.

受託者未經委託者事先評估、核准該等安排及稽核第三方(由委託者或受託者執行)前，不得將契約所委託的任何工作轉託給第三方。受託者及任何第三方間所作的安排，應確保批發運銷提供之資料是依照委託者及受託者原約定的方式。

PIC/S Guide to GDP-chapter 7 Outsourced Activities

7.3 CONTRACT ACCEPTOR 受託者

7.3.4 The Contract Acceptor should refrain from any activity which may adversely affect the quality of the product(s) handled for the Contract Giver.

受託者應避免對受託處理之產品品質可能造成不良影響的任何活動。

7.3.5 The Contract Acceptor must forward any information that can influence the quality of the product(s) to the Contract Giver in accordance with the requirement of the contract.

受託者必須依照合約要求，向委託者提交任何可能影響產品品質之資訊。

Basic requirements for managing outsourced GDP activities
委外管理基要

- Contract Giver is responsible for the outsourced warehousing and/or transportation activities, and ensuring their compliance to the required GDP guidelines

  委託者應對外包的倉儲及/或運輸作業 負完全的責任(全權負責) 確保依循相關GDP準則的規定

- Select and appoint a contract service provider that is capable to deliver the service and meet the GDP guideline requirements
- Contract Giver should have basic Quality System (品質系統) in-place as per requirements in the GDP guidelines below:
- 1.3 Management of Outsourced Activities -委外作業管理
  - The quality system should extend to the control and review of any outsourced activities related to the procurement, holding, supply, import or export of medicinal products. These processes should incorporate quality risk management and include:
  - 品質系統應擴大到任何關於藥品 採購、儲存、供應、輸入或輸出之委外作業的管制及審查。此流程應納入品質風險管理並包含：

Basic requirements for managing outsourced GDP activities
委外管理基要

1.3 Management of Outsourced Activities -委外作業管理

i. assessing the suitability and competence of the Contract Acceptor to carry out the activity, preserving the integrity and security of the medicinal products, and requesting, preserving documentation, and checking authorisation or marketing status, if required;

評估受託者執行活動之適任性與能力、藥品保存之完整性與安全性及文件維護，必要時檢查許可及市場狀態；

ii. defining the responsibilities and communication processes for the quality-related activities of the parties involved;

規範參與品質相關活動者的職責及溝通流程。

iii. monitoring and review of the performance of the Contract Acceptor, identify and implement any required improvements on a regular basis.

定期監測及審查受託者的績效，並識別及執行任何必須改善之處。

Basic requirements for management of outsourced GDP activities
委外管理基要

- Supplier Management Procedure (供應商管理程序)
  - Apply to both new and significant changes in the status of an existing distributor/transporter
  - Evaluation and Qualification of distributor/transporter, Periodic Review and Monitoring
- Contractual Agreement preparation and control (合約協議的製備與管控): Service Agreement, Confidentiality Agreement and Quality Agreement (服務協議、保密協議及品質協議)
- Relevant technical information (相關技術資料): Examples
  - Approved product list with storage condition and special handling instruction if applicable
  - Instructions on packing configuration
  - Safety Data Sheet (SDS, 安全資料表) information for products
- Quality Risk Assessment procedures (品質風險評估程序)

Supplier Management Process (供應商管理程序)

- Step 1 Evaluation (評估)
- Step 2 Qualification (稽核)
- Step 3 Approval (核准)
- Step 4 Periodic Review and Monitoring (定期審查及監控)

Supplier Management Process (供應商管理程序)

Step 1 Evaluation (評估)

- Company profile and service history (公司簡介及歷程)
- Any certification obtained (e.g. GDP, ISO. etc.) (已取得之證書)
- Local specific regulatory requirements (當地法規要求)
- Evaluate quality/supply chain related information of a service prior to pursuing service (評估服務品質/供應鏈相關資訊)
- Quality Risk Assessment (品質風險評估) –type of service, complexity, criticality
- Prequalification questionnaire if needed (如需，資格預審問卷) –selection screening

Supplier Management Process (供應商管理程序)

Step 2 Qualification (稽核)

- Audit of Supplier (供應商查核) -on site (現場) or desk audit (書面查核) pending on quality risk assessment profile
    - Identify any subcontract activities and their compliance management
- Compliance history (符合性經歷) (e.g. history of audit by regulatory authority)
- Quality history of other services provided from the same supplier (if applicable)
- Supplier Quality Agreement (供應商品質協議)
- Regulatory Agency prior approval if applicable

Supplier Management Process (供應商管理程序)

Step 3 Approval (核准) - Approved or not approved

- Identify any training required (if applicable)
- Ensure Service and Quality Agreements (服務及品質協議) all in place

Step 4 Periodic review and Monitoring (定期審查及監控)

- Annual review supplier service/quality metrics (每年審查供應商服務/品質指標)
- Periodic site monitoring and documents review (not limited to official site audit) (定期實地監控及文件審查)
  - Frequency is based on Supplier risk profile and country regulatory requirements
  - Review temperature monitoring data, returned goods evaluation, reject management, deviation, change control, etc.
  - Include review subcontract activities & management
  - Identify any improvement opportunities and provide further training if required
- Periodic Review of Quality Agreement (定期審查品質協議)

Appointing the right contract service provider is the key to compliance management. Quality Agreement (品質協議) is an important tool to define GDP expectation and gain mutual agreement between Contract Giver and Contract Acceptor

Quality Agreement preparation and control procedures
品質協議製備及管控程序

- Contract Giver must have procedures to define the responsibilities and requirements (權責) for preparing, maintaining Quality Agreement between Contract Giver and the Contract Acceptor
  - It is a controlled document with unique number (編號) and version (版次)
  - Scope (範圍) covers all GDP activities outsourced
  - Defines key compliance expectation from Contract Giver
  - Defines Issues/changes required to be communicated and approved by the Contract Giver
  - Complexity depending on the risk associated with the type of service and product
  - It should be reviewed periodically (定期審查)
  - Change history (變更歷史) should be documented
  - Responsible Person's (權責人員) name and contact details must be tabled in the agreement

Quality Agreement for outsourced warehousing/ distribution
委外倉儲及運銷品質協議

- Quality Agreement specifies responsibilities and communication requirements. Some considerations are:
  - Facility, equipment and warehouse operation requirements (設施、設備及倉儲作業)
  - Controlled temperature storage requirements (溫控儲存)
  - Receiving/ Picking/Packing/Dispatching Operations requirements (收貨/揀貨/包裝/出貨作業)
  - Inventory & Record Management requirements (庫存&記錄管理)
  - Quality System requirements (品質系統)
  - Specified that appointment of any sub-contractor (再委託) by Contract Acceptor should obtain prior approval from Contract Giver. Contract Acceptor shall be responsible to ensure that the sub contracted activities meet the Contract Giver's requirements defined in the agreement.
  - Define communication requirements: e.g. issues related to theft (竊盜), damage (損害), integrity (完整性), contamination (汙染), deviations (偏差) of temperature/product specification (溫度/產品規格), major changes (重大變更) (e.g. facility, air handling system, key personnel, company licenses, etc.), regulatory inspection issues (法規檢查), customer complaint (申訴), product recall (回收) etc.

Quality Agreement for outsourced warehousing/ distribution -examples on defining important requirements
委外倉儲及運銷品質協議－重點要求範例

✓Facility, equipment and warehouse operation requirements (設施、設備及倉儲作業要求) :

- Secure area with security procedures that prevent access by unauthorized personnel (避免未授權人員進入管制區)
- Receiving or dispatch bays must be covered to protect product from dust, dirt and rain. (進出貨碼頭免於髒汙及受到天氣影響)
- Segregated areas are identified for Receiving, Quarantine, Rejects, Product Returns and Dispatch. (收貨、隔離、拒用、退回及出貨等各區應適當隔離)
- Protect stored goods from contamination, deterioration, and exposure to direct sunlight. (儲存產品免於受到汙染及暴露於陽光下)
- Pallets must be well maintained and kept in a good state of cleanliness. Only plastic or heat treated wooden pallet (塑膠或熱處理棧板) should be used for storage and shipment of products. Wooden pallets used are to be heat treated per International Standard for Phytosanitary Measures Guideline for Regulating Wood Packaging Material in International Trade (ISPM 15).

Quality Agreement for outsourced warehousing/ distribution -examples on defining important requirements
委外倉儲及運銷品質協議－重點要求範例

✓Facility, equipment and warehouse operation requirements (設施、設備及倉儲作業要求) :

- No eating or drinking is permitted within the distribution facility. (作業區域內不得飲食)
- A pest control program (防蟲鼠計畫) is to be in place to ensure that the facility building is kept free of rodents, vermin, birds, pets and pests.
- Product destruction (產品銷毀) should be conducted by a qualified contractor (合格承包商) in accordance to an approved procedure which complies with the country legal and/or regulatory (當地法規) requirements with due consideration to protection of the environment.
- In the event of subcontracts the delivery or storage of the product (產品運輸及倉儲再委託), the Contract Acceptor (受託商) shall operate and maintain adequate controls and monitoring to ensure appropriate product handling in line with this Agreement (確保產品處理符合協議).
- A Disaster Recovery Plan (災害復原計畫) must be in place in the event of a disaster or emergency which would prevent or adversely affect the provision of services.

Quality Agreement for outsourced warehousing/ distribution -examples on defining important requirements
委外倉儲及運銷品質協議－重點要求範例

✓Controlled Temperature storage requirements (溫控儲存要求)

- The storage conditions (儲存條件) shall be compatible with the storage conditions specified on the Product label (產品標籤) or Contract Giver defined requirements
- Freezer/refrigerator/cold room (冷凍庫/冰箱/冷房) used must be qualified (確效) in accordance to GMP Principle. The qualification report shall be made available for review if requested. Procedure for requalification (再確效)must also be in place.
- Temperature mapping (溫度測繪) shall be conducted for product storage warehouse.
- There should be appropriate back-up arrangements (備援計劃).
- The temperature should be monitored continuously (持續監控) and check daily (每日確認). If any temperature is found to have deviated outside the relevant recommended storage conditions, product should be quarantined and inform Contract Giver for assessment of suitability of the product for sale.
- Temperature controlled refrigeration storage environments must be fitted with both an audio alarm (聲響警報) and a visual signal (視覺訊號) to indicate that refrigeration has failed. The alarm system (警報系統) must ensure that any failures outside normal working hours are addressed immediately. The alarm and visual signal must permit resetting only by an authorized person.
- Instruments used for monitoring temperature shall be calibrated (校正) at least annually (至少每年).

Quality Agreement for outsourced warehousing/ distribution -examples on defining important requirements
委外倉儲及運銷品質協議－重點要求範例

✓ Receiving/ Picking/Packing/Dispatch Operation (收貨/揀貨/包裝/出貨作業)

- Cold chain products (冷鏈產品) must be promptly processed for receipt e.g. within 1 hour from arrival
- Controlled Temperature Products (溫控產品) requiring temperature checks must be performed upon receipt of delivery.
- The receiving check (收貨檢視) should include an inspection on product information (產品資訊), shipment integrity (出貨完整性) and free from contamination (未受汙染) (e.g. oil, chemical, moisture, etc.).
- Product is only distributed to valid customers (合格客戶) in accordance with local market regulatory authority requirements and laws (當地主管機關及法規要求). A documented procedure in place for checking the validity of the customers. Adherence to the process must be reviewed regularly.
- Products returned (退回) from customers must be assessed by trained personnel (經訓練人員) in accordance to documented procedure to ascertain that the products have not been compromised by inappropriate handling and storage conditions. (e.g. broken seals (封緘破損), damaged packaging (包裝受損), potential contamination (潛在污染), inadequate storage conditions (無適當儲存條件), mishandling practice (不當作業).
- Products returned from customers can only be returned to saleable stock (回可銷售庫存) if they meet the acceptable criteria (可接受之標準) and approved by a qualified person (品質管理人員核准).

Quality Agreement for outsourced warehousing/ distribution -examples on defining important requirements
委外倉儲及運銷品質協議－重點要求範例

- Process for identifying suspect falsified products (疑似偽禁藥辨識) and the necessary reporting process must be in place
- Products are transported in such a manner that the transport temperatures (運輸溫度) meet the storage conditions (儲存條件) as indicated on Product labels (產品標籤), at all times.
- Product orders are shipped using validated packaging (確效包裝) which may include dry ice(乾冰), freeze packs(保冷劑), and/or use of qualified refrigerated vehicles (冷藏車) (to ensure that the observable temperature inside the packaging container does not exceed the defined Product maximum temperature/time.
    - Validation must include assessment of seasonal temperature changes (確效應包含季節性變化評估)
- Product are transported in a manner that have no adverse effect on the quality of the products, and offer adequate protection from external influences including contamination; and shall take adequate precautions to prevent spillage, breakage, theft or loss of package integrity.
- Safety and Data sheets (SDS, 安全資料表) should be incorporated in the spill handling (溢漏處理) and emergency processes (突發程序).

Quality Agreement for outsourced warehousing/ distribution -examples on defining important requirements 委外倉儲及運銷品質協議－重點要求範例

✓Inventory & Record Management (庫存&記錄管理)

- Any issues with inventory accuracy (庫存有誤) should be investigated and reported immediately (立即調查及通報) to Contract Giver
- Set up record keeping and record retention (記錄留存) as per country regulator or Contract Giver's requirements whichever is longer.

Quality Agreement for outsourced warehousing/ distribution
委外倉儲及運銷品質協議

✓Quality System requirements (品質系統要求) :

- permits Contract Giver access to premises (進入作業場所) and relevant written documentation (相關書面文件) for the purpose of carrying out an audit (查核) of their facility within reasonable notice
- agrees to work with Contract giver to resolve any issues (共同解決問題) found in line with the regulatory, QA or requirements of the agreement
- there must be a qualified person (品質管理人員) responsible for the control and operation of the Quality System.
- shall undertake an internal self-inspection program (內部自我查核) to ensure their operation maintains compliance to established systems.
- must have a documented procedure for control of changes (變更管制). Significant change must be reported to and approved by contract giver.
- must have a documented procedure for management of deviation (偏差管理) to approved process or product specification. All deviations must be appropriately investigated (調查), documented (文件化) and reviewed (審核) by an authorized person.
- any major deviations (主要偏差) which could impact product integrity and quality (影響產品完整性及品質) must be reported to the Contract Giver.

Quality Agreement for outsourced warehousing/ distribution
委外倉儲及運銷品質協議

- shall ensure that all personnel are adequately trained (適當的訓練) to perform assigned task, with all training records (訓練紀錄) documented accordingly.
- immediately advise Contract Giver of any potential product recall situation (回收情況), market action (市場行動) and/or notification to local health authorities (通報當地主管機關).
- shall maintain a Product recall procedure. Such recall procedure shall include requirements for "mock" recalls (模擬回收) to be conducted periodically.
- shall not perform any repackaging or re-labeling (再包裝/再貼標) of Product without written authorization (未經書面授權) from Contract Giver.

✓ Complaint handling and reporting (申訴處理及通報)

- customer complaints refer to any written, electronic or oral communication (任何書面、電子或口頭通報) that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a Product.
- complaints received from the end user (終端使用者) must be forwarded to Contract Giver within 3 days
- shall notify Complaint Giver within 24 hours for any product complaint that could potentially have an impact on patient safety, including but not limited to, product contamination(污染), mislabeling or misbranding (包裝標示錯誤), tampering (拆封) and counterfeit product (偽禁藥).

Summary

- Supplier Management Procedures (供應商管理程序)
  - Evaluation (評估)
  - Qualification (稽核)
  - Approval (核准) (includes any special conditions required to be fulfilled)
  - On going review and monitoring (審核及監控)
  - Continuous improvements (持續改進)

- Quality Agreement to define expectation, responsibility and communication requirements (品質協議定義權責及通報要求)


QUESTIONS


QUESTIONS?
問題

Management of outsourced transportation service

委外運輸管理

PIC/S Guide to GDP-chapter 9 Transportation 第 9 章運輸

9.1 PRINCIPLE 原則

9.1.1 It is the responsibility of the supplying wholesale distributor to protect medicinal products against breakage, adulteration, theft and to ensure that temperature conditions are maintained within acceptable limits during transport.

批發運銷商的職責，是在供應藥品時防止藥品破損、摻假、竊盜，及確保在運送時維持在可接受的溫度條件下。

9.1.2 Regardless of the mode of transport, it should be possible to demonstrate that the medicines have not been exposed to conditions that may compromise their quality and integrity. A risk-based approach should be utilized when planning transportation.

在任何運送模式下，都應能夠證明藥品不會暴露在可能危害藥品品質及完整性的狀況，且應基於風險考量規劃運輸路線。

PIC/S Guide to GDP-chapter 9 Transportation 第 9 章運輸

9.2 TRANSPORTATION 運輸

9.2.9 Where transportation is performed by a third party, the contract in place should encompass the requirements of Chapter7. Transportation providers should be made aware by the wholesale distributor of the relevant transport conditions applicable to the consignment. Where the transportation route includes unloading and reloading or transit storage at a transportation hub, particular attention should be paid to temperature monitoring, cleanliness and the security of any intermediate storage facilities.

運輸若由第三方執行時，合約應包含第七章之要求，批發運銷商應告知並確保運輸者運輸相關之所有條件。當運輸過程中有上、下貨或經轉運站時，應特別注意其儲存設施之溫度監測、清潔及安全性。

Transportation of medicinal products 藥品運輸

- Supply chain is regarded as storage area by regulator and is reflected in the PIC/S GDP guidelines enforced today.
  - "The transportation arrangements from one location to another should be regarded as an extension of the storage activities. Distributors are required to treat each journey as unique, with the length and complexity, as well as any seasonal variations, being considered when choosing the packing method and mode of distribution"
- It is the responsibility of the supplying wholesale distributor (批發運銷商) to ensure that "the required storage conditions (儲存條件) should be maintained during transportation (運輸期間) within the defined limits as described by the manufacturer (製造商) or on the outer packaging (外包裝) of the product".
- Transport temperature consideration does not limit to just cold-chain product (不局限於冷鏈產品) as ambient products (環境溫度產品) are also temperature sensitive.
- Appropriate use of validated packaging (確效包裝) including consideration for seasonal change (季節性變化) and reconfigurations requirements (重新配置要求)

Important factors for consideration 重要因素考量

- Qualification of contractor involved in transportation should follow a similar approach to qualification of warehouse/distributor
- The method (方法) and time (時間) of transportation, combined with the local seasonal temperatures (當地季節性氣候), temperature control requirements (溫控要求) and the size (體積) and of the load (乘載量) should all be considered when arranging distribution of medicinal products.
- Product type (產品型態) (control drug, vaccine etc.) and storage temperature (儲存溫度) (ambient, <25°C, <5°C or <-20°C)
- Any mixed consignments/risk of contamination (任何共配貨物/汙染風險)
- Any use of intermediate hubs/transit storage (集貨轉運站)
- Temperature mapping (溫度測繪) of the vehicle/temperature monitoring/calibrated devices
- Journey time/length/contingency planning/weather/multi drop deliveries (運輸時間/範圍/應變計畫/天氣/多點配送)
- Security (安全性)
- Cleanliness (清潔)
- Driver training/ employment history (司機訓練/工作經歷)

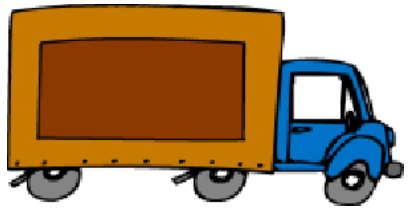
Checklist for evaluating transport service provider (運輸服務提供者評估檢核表)

- Appropriate business license (營業登記執照) for the required product transportation
- Dedicated vehicle (專用車輛) for transportation or vehicle used only for pharmaceutical product transportation
- Procedure for qualification of vehicle, product handling and training of personnel (車輛管理、產品處理及人員訓練程序)
- Procedure for handling of change, deviation, CAPA and reporting (變更管制、偏差、矯正預防及通報處理程序)
- Procedure for Personnel employment check (including criminal record) and training (人員工作經歷確認及訓練程序)
- Temperature compliance management (溫控管理) including cold chain temperature requirements
- Cleaning procedures (清潔程序)
- Maintenance procedures (維護程序)
- Equipment calibration procedures (設備校正程序)
- Procedure for assessment and determining route of transportation (運輸路線評估及確認程序)
- GPS tracking (GPS追蹤) preferred especially cold-chain product transportation
- Security Management (安全管理)

Quality Agreement (品質協議)- defines key requirements

✓ Vehicles and equipment used to transport and handle products should be suitable and be equipped to prevent exposure to conditions that could impact on product integrity and quality.

- Vehicle used must be fully enclosed, protected and secured (密閉及穩固)
- Vehicle used must be qualified to meet the required product storage temperature (符合儲存條件)
- Only qualified vehicle can be used (合格車輛使用)
- Vehicle should be maintained periodically (定期維護)
- Vehicle cleanliness should be maintained daily (每日清潔)
- All temperature measuring devices used should be calibrated at least annually.(溫度測量裝置應至少每年校正)



Quality Agreement (品質協議)- defines key requirements

✓Staff and training (員工及訓練)

- Staff employed are in compliance to country Labor Law (國家勞基法).
- Staff employment process should include criminal conviction check (犯罪紀錄) (e.g. self-declaration or police check)
- Training program (訓練計畫) in place to ensure staff are GDP trained, understand product handling and reporting requirements before commencement of work
- Training records (訓練紀錄) must be kept

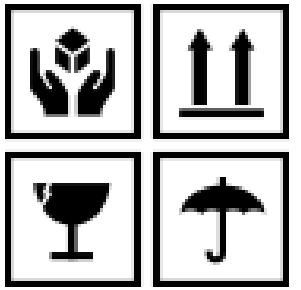
✓Self-inspection program (自我查核計畫)

- Ensure compliance to the established procedures & temperature management requirements

Quality Agreement (品質協議)- defines key requirements

- ✓Any product damage or theft (產品損壞或竊盜) found during transportation should be reported immediately to the distributor (Contract Giver)
- ✓Any temperature deviation (溫度偏差) occurs during transportation should be reported immediately to the distributor
- ✓Transportation of Vaccine and controlled drugs should meet the country regulatory requirements (當地法規要求)
- ✓For cold-chain product transportation(冷鏈產品運輸), storage temperature should be measured(測量), recorded (記錄) for every delivery and review by a responsible person
- ✓There should be backup plan (備援計劃) in place for any breakdown occurrence during transportation to minimize impact on product.

Quality Agreement (品質協議)- defines key requirements



- ✓Product handling and storage (產品處理及儲存)
  - Must strictly follow the handling instruction (處理指示) displayed on the product packaging label (產品包裝標示) .
  - Storage (including transit hub) must be protected from adverse conditions (免於不利情況) e.g. light, water, temperature, dust, chemicals, pests.
  - Product should not be stored next to any products that could potentially contaminate the product including odor(氣味).
  - Product should always be stored above ground and must not be placed on the ground. (不得直接放置於地面上)
  - Avoid exposed products to excessive outdoor temperature (室外溫度) especially under extreme temperature
- ✓Care must be taken at all stages (e.g. transit) to avoid product mix up (混雜) during transportation
- ✓Avoid unnecessary delay during transportation and should be delivered according to the prescribed time (規定時間內送達). Any prolong delay must be reported and investigated.
- ✓Ensure product is received (送達) and signed (簽收) by the customer. Confirm temperature requirements are met. (確保符合溫度要求)

Summary

- 運輸品質管理協議**樣本**
- Evaluation/Qualification/Approval/Quality Agreement(評估/稽核/核准/品質協議)
- Annual review supplier service/quality metrics (每年審核供應商服務/品質指標)
- Conduct Periodic review and monitoring (定期審核及監控)
- Ensure deviation reported are timely and thoroughly investigated and CAPA implemented (確保及時且徹底的調查偏查及執行矯正預防措施)

Management of subcontract warehousing and transportation activities

委外倉儲/運輸再委託第三方之管理

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- Define subcontract activities notification and approval requirements (再委託通知及核准要求) to Contract Giver in the Quality Agreement (品質協議) with the Distributor (Contract Acceptor)
- Review Distributor's supplier management program (審核運銷商之供應商管理計畫) to evaluate competency in appointing/management of their subcontractor (Third party service provider)
- Evaluate subcontractor information (評估再委託商資料) for qualification and if necessary conduct audit on subcontractor as condition for appointment
- Ensure Quality Agreement set up between Distributor and subcontractor meets the Contract Giver's expectation

問題

Thank You

謝謝