國際醫藥品稽查協約組織
人用藥品原料藥優良運銷規範

GUIDELINES ON THE PRINCIPLES OF GOOD DISTRIBUTION PRACTICE OF ACTIVE SUBSTABCES FOR MEDICINAL PRODUCTS FOR HUMAN USE

PI 047-1 (1 July 2018)

目錄

(Table of Contents)

文件歷史沿革 (DOCUMENT HISTORY)

Transposed by SCH from EC document 2015/C 95/01	November 2015 – September 2016
Adoption by Committee of PI 047-1	17-18 April 2018
Entry into force of PI 047-1	1 July 2018

	中譯	原文
前言 (INTRODUCTION)		
	此 PIC/S 指引係以歐盟 EMA GMDP IWG 草擬並經歐盟執委會頒布之 2015/C 95/01 文件為基礎，再經 PIC/S GM(D)P 協和次委員會轉換為 PIC/S 為文件。	The present PIC/S Guidelines are based on EC document 2015/C 95/01, which has been drafted by the EMA GMDP IWG and transposed for PIC/S purpose by the PIC/S Sub-Committee on the Harmonisation of GM(D)P.
	本指引已被 PIC/S 採用作為指導文件。各 PIC/S 會員主管機關得自行決定是否採用作為具有法律約束力之標準。	These guidelines have been adopted by PIC/S as a guidance document. It is up to each PIC/S Participating Authority to decide whether it should become a legally-binding standard.
	本指引依循西藥藥品優良製造規範(第二部：原料藥)第 17 章關於原料藥運銷及西藥優良運銷準則與西藥藥品優良製造規範(第三部：運銷)之相同原則。	These guidelines follow the same principles that underlie the guidelines of the PIC/S PE 009 GMP Guide Part II: Basic Requirements for Active Pharmaceutical Ingredients Chapter 17 with regard to the distribution of active substances and the PIC/S PE 011 Guide to Good Distribution Practice for Medicinal Products.
	本指引提供人用藥品之原料藥輸入商及運銷商獨立指引。本指引除補充西藥藥品優良製造規範(第二部：原料藥)所規定之運銷規範外，亦適用於原料藥製造廠之運銷。	These guidelines provide stand-alone guidance on Good Distribution Practice (GDP) for importers and distributors of active substances for medicinal products for human use. They complement the rules on distribution set out in the PIC/S PE 009 GMP Guide Part II: Basic Requirements for Active Pharmaceutical Ingredients, and apply also to distributors of active substances manufactured by themselves.
	任何原料藥相關之製造活動，包含重分包裝、重標示或分裝，皆應符合西藥藥品優良製造規範(第二部：原料藥)。	Any manufacturing activities in relation to active substances, including re-packaging, re-labelling or dividing up, are subject to PIC/S PE 009 GMP Guide Part II: Basic Requirements for Active Pharmaceutical Ingredients.

	中譯	原文
第一章 範圍 (CHAPTER 1 – SCOPE)		
1.1	本指引適用於人用西藥之原料藥運銷。原料藥係指預定用於藥品之製造的任何物質或物質的混合物，當其使用於製造時，成為該藥品之有效成分，用以發揮藥理學、免疫學、或新陳代謝作用功能，或進行醫療診斷。	These guidelines apply to distribution of active substances, for medicinal products for human use. An active substance is any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action functions or to make a medical diagnosis.
1.2	本指引之目的，原料藥的運銷應包含採購、輸入、儲存、供應或輸出原料藥的所有活動。	For the purpose of these guidelines, distribution of active substances shall comprise all activities consisting of procuring, importing, holding, supplying or exporting active substances, apart from brokering.
1.3	本指引不適用於原料藥的中間產物。	These guidelines do not apply to intermediates of active substances.
第二章 品質系統 (CHAPTER 2 – QUALITY SYSTEM)		
2.1	原料藥運銷商應訂定及維持一套與其活動相關的職責、流程及風險管理原則的品質系統。品質風險管理的流程及應用範例可參見我國西藥藥品優良製造規範附則 20 品質風險管理。	Distributors of active substances should develop and maintain a quality system setting out responsibilities, processes and risk management principles. Examples of the processes and applications of quality risk management can be found in PIC/S PE 009 Guide to Good Manufacturing Practice for Medicinal Products Annex 20 on Quality Risk Management.
2.2	品質系統應有勝任之人員及適當且足夠的作業場所、設備及設施等資源。其應確保：	The quality system should be adequately resourced with competent personnel, and suitable and sufficient premises, equipment and facilities. It should ensure that:
	(i) 原料藥的採購、輸入、儲存、供應或輸出均符合原料藥 GDP 的要求；	(i) active substances are procured, imported, held, supplied or exported in a way that is compliant with the requirements of GDP for active substances;
	(ii) 管理職責經清楚的明定；	(ii) management responsibilities are clearly specified;
	(iii) 原料藥在適當的期間內交付給正確的接受者；	(iii) active substances are delivered to the right recipients within a satisfactory time period;

	中譯	原文
	(iv) 於執行活動的同時進行記錄；	(iv) records are made contemporaneously;
	(v) 偏差要予以文件化與調查；	(v) deviations from established procedures are documented and investigated;
	(vi) 依照品質風險管理原則，採取適當的矯正預防措施(CAPA)，矯正並預防偏差情況；	(vi) appropriate corrective and preventive actions, commonly known as 'CAPA', are taken to correct deviations and prevent them in line with the principles of quality risk management;
	(vii) 可能影響原料藥儲存及運銷之變更應予以評估。	(vii) changes that may affect the storage and distribution of active substances are evaluated.
2.3	發展或修改品質系統時，應考量運銷商活動的規模、架構及複雜性。	The size, structure and complexity of the distributor's activities should be taken into consideration when developing or modifying the quality system.
第三章 人事 (CHAPTER 3 – PERSONNEL)		
3.1	運銷商應在其執行運銷活動的每一個場所指定一名人員，而該名人員應有指定的權限及職責以確保品質系統的執行及維護。被指定之人員應親自履行其職責。被指定之人員可指派職務代理人，但仍需擔負此責任。	The distributor should designate a person at each location where distribution activities are performed who should have defined authority and responsibility for ensuring that a quality system is implemented and maintained. The designated person should fulfil his responsibilities personally. The designated person can delegate duties but not responsibilities.
3.2	參與原料藥運銷之所有人員應以書面明定其職責。人員應接受原料藥 GDP 規範之要求訓練。且應具有適當的能力及經驗以確保原料藥皆經適當的處理、儲存及運銷。	The responsibilities of all personnel involved in the distribution of active substances should be specified in writing. The personnel should be trained on the requirements of GDP for active substances. They should have the appropriate competence and experience to ensure that active substances are properly handled, stored and distributed.
3.3	人員應依照書面程序及訓練計畫，接受與其職務相關的職前及持續訓練。	Personnel should receive initial and continuing training relevant to their role, based on written procedures and in accordance with a written training programme.
3.4	應保存所有訓練紀錄，且訓練的有效性應定期評估及文件化。	A record of all training should be kept, and the effectiveness of training should be periodically assessed and documented.

	中譯	原文
第四章 文件 (CHAPTER 4 – DOCUMENTATION)		
4.1	文件包含以紙本或電子形式呈現的所有書面程序、指令、合約、紀錄及數據，文件應能立即取得或取回。運銷商遵循此指引相關之所有文件應於主管機關要求時即可提供。	Documentation comprises all written procedures, instructions, contracts, records and data, in paper or in electronic form. Documentation should be readily available or retrievable. All documentation related to compliance of the distributor with these guidelines should be made available on request of competent authorities.
4.2	關於運銷商活動範圍之文件應使員工充分地理解，並以員工可瞭解的語言書寫，書寫文件應使用明確的語言且應無錯誤。	Documentation should be sufficiently comprehensive with respect to the scope of the distributor's activities and in a language understood by personnel. It should be written in clear, unambiguous language and be free from errors.
4.3	文件中所進行的任何變更應簽章並註明日期；該變更應允許讀取原來的資訊。適當時，更改理由應記錄之。	Any alteration made in the documentation should be signed and dated; the alteration should permit the reading of the original information. Where appropriate, the reason for the alteration should be recorded.
4.4	每位人員應可隨時取得與其執行作業相關之文件。	Each employee should have ready access to all necessary documentation for the tasks executed.
程序 (Procedures)		
4.5	書面程序應描述影響原料藥品質的運銷活動，可能包括貨物的接收與檢視、儲存、作業場所的清潔和維護(含防蟲鼠)、儲存條件的紀錄、庫存與轉運貨物的安全性、可銷售庫存的移開、退回品的處理和回收計畫等。	Written procedures should describe the distribution activities which affect the quality of the active substances. This could include receipt and checking of deliveries, storage, cleaning and maintenance of the premises (including pest control), recording of the storage conditions, security of stocks on site and of consignments in transit, withdrawal from saleable stock, handling of returned products, recall plans, etc.
4.6	程序應由負責品質系統之人員核准、簽章並註明日期。	Procedures should be approved, signed and dated by the person responsible for the quality system.
4.7	應特別留意使用有效並經核准的作業程序。文件應定期審查及更新，版本管制應納入作業程序內；文件經改版後，系統應有防止不慎使用先前版本的功能，被取代或廢棄的程序應從	Attention should be paid to the use of valid and approved procedures. Documents should be reviewed regularly and kept up to date. Version control should be applied to procedures. After revision of a document a system should exist to

	中譯	原文
	工作站移除及歸檔。	prevent inadvertent use of the superseded version. Superseded or obsolete procedures should be removed from workstations and archived.
紀錄 (Records)		
4.8	紀錄應清楚，並於每一項作業執行時記錄，記錄的方式需可追溯所有重要活動或事件。紀錄應保存至該相關批次原料藥末效日期後至少一年。對於再驗日期之原料藥，紀錄應保存至該批次完全運銷後至少三年。	Records should be clear, be made at the time each operation is performed and in such a way that all significant activities or events are traceable. Records should be retained for at least 1 year after the expiry date of the active substance batch to which they relate. For active substances with retest dates, records should be retained for at least 3 years after the batch is completely distributed.
4.9	每次採購和銷售紀錄應予以保存，清楚記錄採購或供應日期、原料藥名稱、接收或供應的批號及數量，以及供應商和原製造廠(如不相同時)或貨運代理商及/或收貨人的名稱及地址。紀錄應確保產品來源及目的地的可追溯性，使得原料藥供應商或其隨同的供應商皆得以藉此辨識。應保存並可取得的紀錄包括:	Records should be kept of each purchase and sale, showing the date of purchase or supply, name of the active substance, batch number and quantity received or supplied, and name and address of the supplier and of the original manufacturer, if not the same, or of the shipping agent and/or the consignee. Records should ensure the traceability of the origin and destination of products, so that all the suppliers of, or those supplied with, an active substance can be identified. Records that should be retained and be available include:
	(i) 供應商、原製造廠、貨運代理商及/或收貨人的識別；	(i) identity of supplier, original manufacturer, shipping agent and/or consignee;
	(ii) 供應商、原製造廠、貨運代理商及/或收貨人的地址；	(ii) address of supplier, original manufacturer, shipping agent and/or consignee;
	(iii) 採購訂單；	(iii) purchase orders;
	(iv) 裝貨憑單/提貨單、運輸及運銷紀錄；	(iv) bills of lading, transportation and distribution records;
	(v) 接收文件；	(v) receipt documents;
	(vi) 原料藥的名稱或指定名稱；	(vi) name or designation of active substance;
	(vii) 製造廠的批號；	(vii) manufacturer’s batch number;
	(viii) 分析證明書，包含原製造廠的證明書；	(viii) certificates of analysis, including those of the original manufacturer;
	(ix) 再驗日期或末效日期。	(ix) retest or expiry date.

	中譯	原文
第五章 作業場所及設備 (CHAPTER 5 – PREMISES AND EQUIPMENT)		
5.1	作業場所及設備應適當且足夠，以確保原料藥適當的儲存及防止污染(如麻醉藥、高致敏性物質、高藥理活性或毒性的物質)及原料藥的運銷。	Premises and equipment should be suitable and adequate to ensure proper storage, protection from contamination, e.g. narcotics, highly sensitising materials, materials of high pharmacological activity or toxicity, and distribution of active substances.
5.2	應有適當的保全以防止未經授權的人員進入。	They should be suitably secure to prevent unauthorised access.
5.3	確保原料藥品質特性之必要監測設備應在可追溯的標準下依照核定的時程進行校正。	Monitoring devices that are necessary to guarantee the quality attributes of the active substance should be calibrated according to an approved schedule against certified traceable standards.
第六章 作業 (CHAPTER 6 – OPERATIONS)		
訂單 (Orders)		
6.1	採購原料藥時，製造廠、輸入商或運銷商須依國內法規進行登記。	Where active substances are procured from a manufacturer, importer or distributor that manufacturer, importer or distributor should be registered according to national law.
收貨 (Receipt)		
6.2	原料藥收貨區域應保護原料藥卸貨時免於受到天氣之影響。收貨區域應與儲存區域隔離。交付的原料藥應在收貨時檢查核對，以確認：	Areas for receiving active substances should protect deliveries from prevailing weather conditions during unloading. The reception area should be separate from the storage area. Deliveries should be examined at receipt in order to check that:
	(i) 容器未受損；	(i) containers are not damaged;
	(ii) 所有安全封緘皆完整且未有竄改跡象；	(ii) all security seals are present with no sign of tampering;
	(iii) 標示之正確性，包括供應商使用之名稱與廠內名稱不相同時，其間的關聯性；	(iii) correct labelling, including correlation between the name used by the supplier and the in-house name, if these are different;
	(iv) 可取得的必要資訊，例如分析證明書等；及	(iv) necessary information, such as a certificate of analysis, is available; and
	(v) 接收之原料藥與訂單一致。	(v) the active substance and the consignment correspond to the order.
6.3	封緘破損、包裝損壞或疑似可能遭受	Active substances with broken seals, damaged

	中譯	原文
	污染的原料藥應採實體方式或同等效力之電子系統加以隔離，並調查其原因。	packaging, or suspected of possible contamination should be quarantined either physically or using an equivalent electronic system and the cause of the issue investigated.
6.4	採取特定儲存方式的原料藥，如麻醉藥或特定儲存溫度或濕度之產品等，應立即辨識並依書面指示和相關法律規定進行儲存。	Active substances subject to specific storage measures, e.g. narcotics and products requiring a specific storage temperature or humidity, should be immediately identified and stored in accordance with written instructions and with relevant legislative provisions.
6.5	當運銷商懷疑其採購或輸入之原料藥可能涉及偽、禁藥時，其應以實體方式或同等效力之電子系統加以隔離，並通知主管機關。	Where the distributor suspects that an active substance procured or imported by him is falsified, he should segregate it either physically or using an equivalent electronic system and inform the national competent authority of the country in which he is registered.
6.6	拒用之原料應加以標示、管制及隔離，以免於其未經授權使用於製造及進一步的運銷。銷毀活動的紀錄應可立即取得。	Rejected materials should be identified, controlled and quarantined to prevent their unauthorised use in manufacturing and their further distribution. Records of destruction activities should be readily available.
儲存 (Storage)		
6.7	原料藥的儲存應遵照製造廠規定的條件，如必要時溫度和濕度控制，並採取以預防污染及/或混雜的方式。儲存條件應予以監測並留存紀錄。此紀錄應由該負責品質系統之人員定期審查。	Active substances should be stored under the conditions specified by the manufacturer, e.g. controlled temperature and humidity when necessary, and in such a manner to prevent contamination and/or mix up. The storage conditions should be monitored and records maintained. The records should be reviewed regularly by the person responsible for the quality system.
6.8	當需要特定儲存條件時，儲存區域應予驗證，並在規定的範圍內作業。	When specific storage conditions are required, the storage area should be qualified and operated within the specified limits.
6.9	儲存設施應保持潔淨並避免雜物、灰塵及蟲鼠。應採取足夠的預防措施以防止溢漏或破損、微生物侵入及交叉汙染。	The storage facilities should be clean and free from litter, dust and pests. Adequate precautions should be taken against spillage or breakage, attack by micro-organisms and cross-contamination.

	中譯	原文
6.10	應建立一套系統以確保庫存品週轉，如「先到期（再驗日期）先出貨」，並定期及經常確認該系統正確運作。電子化倉儲管理系統應經過確效。	There should be a system to ensure stock rotation, e.g. 'first expiry (retest date), first out', with regular and frequent checks that the system is operating correctly. Electronic warehouse management systems should be validated.
6.11	超過末效日期的原料藥應以實體方式或同等效力之電子系統從核准之庫存品隔離且不得再供應。	Active substances beyond their expiry date should be separated, either physically or using an equivalent electronic system, from approved stock and not be supplied.
6.12	原料藥的儲存或運輸委外時，運銷商應確保受託者明瞭並依循適當的儲存及運送條件。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。未經委託者書面授權，受託者不得將契約所委託的任何工作轉委託。	Where storage or transportation of active substances is contracted out, the distributor should ensure that the contract acceptor knows and follows the appropriate storage and transport conditions. There must be a written contract between the contract giver and contract acceptor, which clearly establishes the duties of each party. The contract acceptor should not subcontract any of the work entrusted to him under the contract without the contract giver's written authorisation.
交貨給客戶 (Delivers to customers)		
6.13	供應原料藥僅能由依國內法規登記的原料藥運銷商供應給其他運銷商、製造廠。	Supplies should be made only by distributors of active substances registered according to national law to other distributors, manufacturers or to dispensing pharmacies.
6.14	原料藥應依製造廠規定的條件運輸，並採取不會對品質造成有害影響的方式。產品、批次及容器識別隨時維持。所有原裝容器的標籤皆應保持可讀取的狀態。	Active substances should be transported in accordance with the conditions specified by the manufacturer and in a manner that does not adversely affect their quality. Product, batch and container identity should be maintained at all times. All original container labels should remain readable.
6.15	應備有可易於辨識每批原料藥之運銷的系統，以使其得以回收。	A system should be in place by which the distribution of each batch of active substance can be readily identified to permit its recall.
資訊的移轉 (Transfer of information)		
6.16	運銷商得知潛在會造成供應中斷的任何資訊或事件，皆應通知相關客戶。	Any information or event that the distributor becomes aware of, which have the potential to cause an interruption to supply, should be notified

	中譯	原文
		to relevant customers.
6.17	運銷商應將從原料藥製造廠收到的所有產品品質或法規資訊移轉給客戶，並將從客戶收到的資訊移轉給原料藥製造廠。	Distributors should transfer all product quality or regulatory information received from an active substance manufacturer to the customer and from the customer to the active substance manufacturer.
6.18	供應原料藥給客戶的運銷商，應提供原料藥之原製造廠的名稱與地址，及其所供應的批號。來自製造廠之原始分析證明書的副本亦應提供給客戶。	The distributor who supplies the active substance to the customer should provide the name and address of the original active substance manufacturer and the batch number(s) supplied. A copy of the original certificate of analysis from the manufacturer should be provided to the customer.
6.19	運銷商應依主管機關之要求，提供原料藥之原製造廠的身分識別。原製造廠可直接或透過被授權之代理商回應主管機關（在此，「被授權」意指經由製造廠授權）。	The distributor should also provide the identity of the original active substance manufacturer to competent authorities upon request. The original manufacturer can respond to the competent authority directly or through its authorised agents. (In this context 'authorised' refers to authorised by the manufacturer.)
6.20	分析證明書的特定規範詳述參照西藥藥品優良製造規範(第二部:原料藥) PE 009 第 11.4 節。	The specific guidance for certificates of analysis is detailed in Section 11.4 of PIC/S GMP Guide Part II: Basic Requirements for Active Pharmaceutical Ingredients PE 009.
第七章 退回、申訴及回收 (CHAPTER 7 – RETURNS, COMPLIAINTS AND RECALLS)		
7.1	退回的原料藥應予識別並隔離以待調查。	Returned active substances should be identified as such and quarantined pending investigation.
7.2	已離開運銷商管理之原料藥，僅有在確認符合以下所有情況，才能退回到可銷售品庫存：	Active substances which have left the care of the distributor, should only be returned to approved stock if all of the following conditions are met:
	(i) 該原料藥仍保存在原未開封的容器中，並保有所有原安全封緘且仍呈現良好狀態；	(i) the active substance is in the original unopened container(s) with all original security seals present and is in good condition;
	(ii) 經證明該原料藥皆在適當的條件下儲存及處理。為此目的，應取得客戶提供的書面資訊；	(ii) it is demonstrated that the active substance has been stored and handled under proper conditions. Written information provided by the customer should be available for this purpose;
	(iii) 可接受的剩餘架儲期；	(iii) the remaining shelf life period is acceptable;
	(iv) 該原料藥已由接受充分地訓練	(iv) the active substance has been examined and

	中譯	原文
	且經授權之勝任人員進行檢查及評估；	assessed by a person trained and authorised to do so;
	(v) 未發生資訊/可追溯性的遺失。	(v) no loss of information/traceability has occurred.
	此評估應考慮該原料藥的性質、其所須之任何特殊儲存條件，及供應後經過的時間。必要時，若對於退回之原料藥的品質有任何疑慮時，應尋求製造廠的建議。	This assessment should take into account the nature of the active substance, any special storage conditions it requires, and the time elapsed since it was supplied. As necessary and if there is any doubt about the quality of the returned active substance, advice should be sought from the manufacturer.
7.3	退回的原料藥之紀錄應予保存。就每一退回物件之文件應包括：	Records of returned active substances should be maintained. For each return, documentation should include:
	(i) 將原料藥退回之原收貨人姓名及地址；	(i) name and address of the consignee returning the active substances;
	(ii) 原料藥名稱或指定名稱、原料藥批號和退回數量；	(ii) name or designation of active substance, active substance batch number and quantity returned;
	(iii) 退回的理由；	(iii) reason for return;
	(iv) 退回的原料藥使用或處置及其評估紀錄。	(iv) use or disposal of the returned active substance and records of the assessment performed.
7.4	僅有受過適當訓練及授權的人員才可放行原料藥回到庫存。退回至可銷售品庫存之原料藥，其放置應依庫存周轉系統有效運作。	Only appropriately trained and authorised personnel should release active substances for return to stock. Active substances returned to saleable stock should be placed such that the stock rotation system operates effectively.
申訴及回收 (Complaints and recalls)		
7.5	無論是以口頭或書面收到之所有申訴，均應依照書面程序加以記錄及調查。對於有關原料藥品質申訴之事件，運銷商應與原料藥之原製造廠檢討該申訴，以決定是否與可能已收到該原料藥之其他客戶，及/或與主管機關啟動任何進一步的行動。申訴原因的調查應由適當之當事人執行並予以文件化。	All complaints, whether received orally or in writing, should be recorded and investigated according to a written procedure. In the event of a complaint about the quality of an active substance the distributor should review the complaint with the original active substance manufacturer in order to determine whether any further action, either with other customers who may have received this active substance or with the competent authority, or both, should be initiated.

	中譯	原文
		The investigation into the cause for the complaint should be conducted and documented by the appropriate party.
7.6	申訴的紀錄應包含：	Complaint records should include:
	(i) 申訴者的姓名及地址；	(i) name and address of complainant;
	(ii) 提出該申訴的人之姓名、頭銜(如合適時)及電話號碼；	(ii) name, title, where appropriate, and phone number of person submitting the complaint;
	(iii) 申訴的本質，含原料藥的名稱及批號；	(iii) complaint nature, including name and batch number of the active substance;
	(iv) 收到申訴的日期；	(iv) date the complaint is received;
	(v) 初始採取的行動，含採取該行動之日期及人員的身分；	(v) action initially taken, including dates and identity of person taking the action;
	(vi) 任何所採取之追蹤行動；	(vi) any follow-up action taken;
	(vii) 提供給原申訴人的回應，含送出回應的日期；	(vii) response provided to the originator of complaint, including the response date;
	(viii) 對於該批次原料藥的最終決定。	(viii) final decision on active substance batch.
7.7	為評估趨勢、產品相關的申訴頻度及嚴重性，以便採取追加的與立即的（合適時）改正措施，申訴紀錄應予保存。 這些紀錄皆應在主管機關查核時提供。	Records of complaints should be retained in order to evaluate trends, product related frequencies, and severity with a view to taking additional, and if appropriate, immediate corrective action. These should be made available during inspections by competent authorities.
7.8	在申訴經提交給原料藥之原製造廠時，運銷商所保存之紀錄，應包含從原料藥之原製造廠所收到的任何回應，包括日期及提供的資訊。	Where a complaint is referred to the original active substance manufacturer, the record maintained by the distributor should include any response received from the original active substance manufacturer, including date and information provided.
7.9	有嚴重或可能危及生命之情況時，應通知當地、國家及/或國際主管機關並徵詢其意見。	In the event of a serious or potentially life-threatening situation, local, national, and/or international authorities should be informed and their advice sought.
7.10	應有書面程序，界定原料藥應考慮回收的情況。	There should be a written procedure that defines the circumstances under which a recall of an active substance should be considered.
7.11	回收程序應指定參與評估該資訊的人員、應如何啟動回收、該回收應被	The recall procedure should designate who should be involved in evaluating the information, how a

	中譯	原文
	通知的對象，以及應如何處理回收品。 被指定之人員（參照第 3.1 節）應參與回收。	recall should be initiated, who should be informed about the recall, and how the recalled material should be treated. The designated person (cf. Section 3.1) should be involved in recalls.
第八章 自我查核 (CHAPTER 8 – SELF-INSPECTIONS)		
8.1	為監測此指引之執行與符合性，運銷商應執行並記錄自我查核。	The distributor should conduct and record self-inspections in order to monitor the implementation of and compliance with these guidelines.
8.2	應依照核定的時程表執行定期的自我查核。	Regular self-inspections should be performed in accordance with an approved schedule.

附件 (ANNEX)

適用於此指引之術語表 (Glossary of terms applicable to these guidelines)

用詞	中譯	原文
Batch 批	在一個製程中或一系列製程中所生產之特定量的物質，因此預期在規定的限量內是均質的。在連續的生產中，一個批可能是相當於該生產過程所界定的段落。批量得以一固定量或以在固定時間間隔內所生產之量來界定。	A specific quantity of material produced in a process or series of processes so that it is expected to be homogeneous within specified limits. In the case of continuous production, a batch may correspond to a defined fraction of the production. The batch size can be defined either by a fixed quantity or by the amount produced in a fixed time interval.
Batch number 批號	識別一個批次之數字、文字及/或符號的獨特組合。藉此，可以確定其生產及運銷的歷史。	A unique combination of numbers, letters and/or symbols that identifies a batch (or lot) and from which the production and distribution history can be determined.
Calibration 校正	一特定儀器或裝置，與對照標準品或可追溯標準品在適當量測範圍內所產生的結果進行比較，證明其產生之結果在規定限值內。	The demonstration that a particular instrument or device produces results within specified limits by comparison with those produced by a reference or traceable standard over an appropriate range of measurements.
Consignee 收貨人	透過陸、海或空運方式接受貨物之人。	The person to whom the shipment is to be delivered whether by land, sea or air.
Contamination 汙染	原料、中間產物或原料藥在生產、抽樣、分包裝或重分包裝、儲存或運送中，遭受到化學或微生物學特性之不純物或異物混入。	The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a raw material, intermediate, or active substance during production, sampling, packaging or repackaging, storage or transport.
Distribution of active substances 原料藥的運銷	包含採購、輸入、儲存、供應或輸出原料藥的所有活動。	All activities consisting of procuring, importing, holding, supplying or exporting of active substances, apart from brokering.
Deviation 偏差	偏離經核准之指令或既定之標準。	Departure from an approved instruction or established standard.

用詞	中譯	原文
Expiry date 末效日期	在原料藥之容器/標籤上所載之日期，指定該原料藥於所指定期間內，如儲存在所界定的條件下，可期待維持在既定架儲期規格內，並且在該日期之後不得使用。	The date placed on the container/labels of an active substance designating the time during which the active substance is expected to remain within established shelf life specifications if stored under defined conditions and after which it should not be used.
Falsified active substance 偽、禁原料藥	任何具有下列不實陳述之原料藥： a) 原料藥的識別，包括其包裝及標示、名稱或關於任何成分的組成及這些成分的效力； b) 其來源，包括其製造廠、製造國家、其原產國；或 c) 其紀錄，包括與運銷途徑相關的紀錄與文件。	Any active substance with a false representation of: a) its identity, including its packaging and labelling, its name or its components as regards any of the ingredients and the strength of those ingredients; b) its source, including its manufacturer, its country of manufacture, its country of origin; or c) its history, including the records and documents relating to the distribution channels used.
Holding 儲存	儲存原料藥。	Storing active substances.
Procedure 程序	直接或間接原料藥之運銷有關之待執行的作業、待採取之預防及待運用之措施的文件化說明。	A documented description of the operations to be performed, the precautions to be taken and measures to be applied directly or indirectly related to the distribution of an active substance.
Procuring 採購	從製造廠、輸入商或其他運銷商取得、獲得、或購買原料藥。	Obtaining, acquiring, purchasing or buying active substances from manufacturers, importers or other distributors.
Quality risk management 品質風險管理	在產品生命週期間針對原料藥品質風險之評估、管制、溝通及審查的系統化流程。	A systematic process for the assessment, control, communication and review of risks to the quality of an active substance across the product lifecycle.
Quality system 品質系統	執行品質政策及確保符合品質目標之系統各方面的總稱(ICH Q9)。	The sum of all aspects of a system that implements quality policy and ensures that quality objectives are met (ICH Q9).

用詞	中譯	原文
Quarantine 隔離/待驗	指物質被以實體或其他有效方式隔離的狀態，以留待後續核准或拒用的決定。	The status of materials isolated physically or by other effective means pending a decision on the subsequent approval or rejection.
Retest date 再驗日期	當一原料應當再度檢驗，以確保其仍然適合使用的日期。	The date when a material should be re-examined to ensure that it is still suitable for use.
Supplying 供應	所有提供、銷售、捐贈原料藥至運銷商或藥品製造廠的活動。	All activities of providing, selling, donating active substances to distributors, pharmacists, or manufacturers of medicinal products.
Signed (signature) 經…簽署 (簽名)	執行一特定行動或審查之個人紀錄。該紀錄得為姓名之首字母、完整手寫簽名、私章或經認證且可靠的電子簽章。	The record of the individual who performed a particular action or review. This record can be initials, full handwritten signature, personal seal, or authenticated and secure electronic signature.
Transport (transportation) 運送 (運輸)	在兩個地點之間移動原料藥，其存放未超過不當的時間。	Moving active substances between two locations without storing them for unjustified periods of time.
Validation 確效	係一個經文件化之計畫，對一特定製程、方法或系統，提供高度保證其會持續一致地產生符合預定允收標準的結果。	A documented program that provides a high degree of assurance that a specific process, method, or system will consistently produce a result meeting pre-determined acceptance criteria.