國際醫藥品稽查協約組織（PIC/S）
藥品優良製造規範指導手冊
（總則）

Guide to Good Manufacturing Practice
（GMP）for Medicinal Products
（Part I）

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總 則（Part I）

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第一章　品質管理（QUALITY MANAGEMENT）

原則（PRINCIPLE）	
The holder of a manufacturing authorisation must manufacture medicinal products so as to ensure that they are fit for their intended use, comply with the requirements of the marketing authorisation and do not place patients at risk due to inadequate safety, quality or efficacy. The attainment of this quality objective is the responsibility of senior management and requires the participation and commitment by staff in many different departments and at all levels within the company, by the company's suppliers and by the distributors.	製造許可的持有者，應依上市許可的要求製造藥品，且不由於安全性、品質或有效性之欠缺而使病人陷於危險，以確保該藥品適合其預定效用。該品質目標的達成是高層管理者的責任，需要公司內許多不同部門與所有階層之人員，以及公司之供應商與經銷商的參與和許諾。
To achieve the quality objective reliably there must be a comprehensively designed and correctly implemented system of Quality Assurance Incorporating Good Manufacturing Practice and thus Quality Control. It should be fully documented and its effectiveness monitored. All parts of the Quality Assurance systems should be adequately resourced with competent personnel, and suitable and sufficient premises, equipment and facilities. There are additional legal responsibilities for the holder of the manufacturing a authorisation and for the authorised person(s).	為可靠達成該品質目標，應有全面設計並正確實施的品質保證系統。該系統涵蓋優良製造準則與品質管制，應充分文件化，並監測其效果。品質保證系統的所有部門應適當配置能勝任的人員，以及合適且足夠的廠房、設備與設施。製造許可的持有者及被授權人還有其他法律責任。
1.1. The basic concepts of Quality Assurance, Good Manufacturing Practice and Quality Control are inter-related. They are described here in order to emphasis their relationships and their fundamental importance to the production and control of medicinal products.	1.1. 品質保證、優良製造準則和品質管制的基本概念是相互關聯的。在本章中將其描述，以強調其間的關係及其對於藥品之生產和管制的重要性。

品質保證（QUALITY ASSURANCE）	
1.2. Quality Assurance is a wide ranging concept which covers all matters which individually or collectively influence the quality of a product. It is the sum total of the organised arrangements made with the object of ensuring that medicinal products are of the quality required for their intended use. Quality Assurance therefore incorporates Good Manufacturing Practice plus other factors outside the scope of this Guide. The system of Quality Assurance appropriate for the manufacture of medicinal products should ensure that:	1.2. 品質保證是一個廣泛的概念。該概念涵蓋單獨或共同影響一個產品之品質的一切事項。品質保證是有組織之安排的總和，以確保藥品具有預定效用所需之品質為其目標。因此，品質保證係結合優良製造準則加上本指引範圍外的其他因素而成。該適合於藥品製造的品質保證系統應確保下列事項：
i. medicinal products are designed and developed in a way that takes account of the requirements of Good Manufacturing Practice and Good Laboratory Practice;	i. 藥品之設計與開發方式應考慮優良製造準則及優良實驗室準則(ＧＬＰ)的要求；
ii. production and control operations are clearly specified and Good Manufacturing Practice adopted;	ii. 生產和管制作業應予清楚界定，並採用優良製造準則；
iii. managerial responsibilities are clearly specified;	iii. 管理責任應予清楚界定；
iv. arrangements are made for the manufacture, supply and use of the correct starting and packaging materials;	iv. 對於正確之原料與包裝材料的製造、供應與使用做出安排；
v. all necessary controls on intermediate products, and any other in-process controls and validations are carried out;	v. 半製品/中間產品的一切必要管制，以及任何其他製程中管制與確效均已執行；
vi. the finished product is correctly processed and checked, according to the defined procedures;	vi. 最終產品是依界定的程序予以正確地操作與核對；
vii. medicinal products are not sold or supplied before an authorised person has certified that each production batch has been produced and controlled in accordance with the requirements of the	vii. 在被授權人證實每一生產批次皆已依上市許可及任何有關藥品之生產、管制與放行的法規之要求生產與管制前，不得將藥品銷售與供應；

marketing authorisation and any other regulations relevant to the production, control and release of medicinal products;	
viii. satisfactory arrangements exist to ensure, as far as possible, that the medicinal products are stored, distributed and subsequently handled so that quality is maintained throughout their shelf life;	viii. 有令人滿意的安排，以儘可能確保藥品之儲存、運銷及後續的處理，從而在其架儲期間能維持其品質；
ix. there is a procedure for self-inspection and/or quality audit which regularly appraises the effectiveness and applicability of the quality assurance system.	ix. 有一套定期評估品質保證系統之有效性及適用性的自我查核及/或品質稽查的程序。
藥品優良製造準則（GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS (GMP) ）	
1.3. Good Manufacturing Practice is that part of Quality Assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation or product specification. Good Manufacturing Practice is concerned with both production and quality control. The basic requirements of GMP are that:	1.3. 優良製造準則是品質保證的一部分，用以確保一貫地生產及管制達到適合其預定效用及上市許可或產品規格所要求之品質標準的藥品。優良製造準則涉及生產與品質管制兩者。GMP 的基本要求為：
i. all manufacturing processes are clearly defined, systematically reviewed in the light of experience and shown to be capable of consistently manufacturing medicinal products of the required quality and complying with their specifications:	i. 一切製造過程均已清楚界定，按照經驗有系統地檢討，顯出其能一貫地製造具有要求的品質並符合其規格的藥品。
ii. critical steps of manufacturing processes and significant changes to the process are validated;	ii. 製程的關鍵步驟與對於製程的重大變更是經過確效的；
iii. all necessary facilities for GMP are provided including:	iii. 提供之優良製造準則所需條件包括：
a. appropriately qualified and trained personnel;	a. 經適當資格檢定與訓練的人員；

b. adequate premises and space;	b. 足夠的廠房與作業空間；
c. suitable equipment and services;	c. 適當的設備及支援服務；
d. correct materials, containers and labels;	d. 正確的原物料、容器和標籤；
e. approved procedures and instructions;	e. 經核定的程序和指令；
f. suitable storage and transport;	f. 適當的儲存及運送；
iv. instructions and procedures are written in an instructional form in clear and unambiguous language, specifically applicable to the facilities provided;	iv. 以清楚且不含糊的文筆，將指令及程序書寫成指導性的方式。這特別適用於提供的設施；
v. operators are trained to carry out procedures correctly;	v. 訓練操作者正確地執行程序；
vi. records are made, manually an(and)/or by recording instruments, during manufacture which demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the product was as expected. Any significant deviations are fully recorded and investigated;	vi. 在製造中，以手工及/或記錄儀器製作紀錄，以證明界定的程序與指令要求之一切步驟事實上皆已執行，以及產品的數量與品質是如其所預期。任何重大的偏差均已完整記錄並調查。
vii. records of manufacture including distribution which enable the complete history of a batch to be traced, are retained in a comprehensible and accessible form;	vii. 可以追蹤一個批次之完整歷程的製造紀錄，包含其運銷在內，應以一種可理解與可取得的形式保存；
viii. the distribution (wholesaling) of the products minimises any risk to their quality;	viii. 產品的運銷(批發)應使其對於產品品質的任何危險降到最小。
ix. a system is available to recall any batch of product, from sale or supply;	ix. 應有一套可以從銷售或供應點上回收任何批次之產品的回收系統。
x. complaints about marketed products are examined, the causes of quality defects investigated and appropriate measures taken in respect of the defective products and to prevent re-occurrence.	x. 審查關於上市產品的申訴，調查品質瑕疵的原因，且對於該瑕疵產品採取適當的措施並防止其再度發生。

品質管制（QUALITY CONTROL）	
1.4. Quality Control is that part of Good Manufacturing Practice which is concerned with sampling, specifications and testing, and with the organisation, documentation and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their quality has been judged to be satisfactory. The basic requirements of Quality Control are that:	1.4. 品質管制是優良製造準則的一部分。這與抽樣、規格及測試有關，也與組織、文件與放行程序有關，用以確保已確實執行必要且相關的試驗，並且確保品質非經判定滿意，原物料不會放行使用，產品不會放行銷售或供應。品質管制的基本要求是：
i. adequate facilities, trained personnel and approved procedures are available for sampling, inspecting and testing starting materials, packaging materials, intermediate, bulk, and finished products, and where appropriate for monitoring environmental conditions for GMP purposes;	i. 具有足夠的設施、受過訓練的人員及經認可的程序，以供抽樣、查核和測試原料、包裝材料、半製品/中間產品、待分/包裝產品與最終產品，並在合適時為優良製造準則之目的監測環境條件。
ii. samples of starting materials, packaging materials, intermediate products, bulk products and finished products are taken by personnel and by methods approved by Quality Control;	ii. 原料、包裝材料、半製品/中間產品、待分/包裝產品和最終產品的樣品應由品質管制部門認可的人員及方法抽取之；
iii. test methods are validated;	iii. 試驗方法是經過確效的；
iv. records are made, manually and/or by recording instruments which demonstrate that all the required sampling, inspecting and testing procedures were actually carried out. Any deviations are fully recorded and investigated;	iv. 應以手工及/或記錄儀器製作紀錄，證明一切要求的抽樣、查核及測試程序皆已確實執行。任何偏差/偏離均完整記錄並調查。
v. the finished products contain active ingredients complying with the qualitative and quantitative composition of the marketing authorisation, are of the purity required, and are enclosed within their proper container and correctly labelled;	v. 含符合上市許可的定性與定量組成之有效成分的最終產品應具有要求的純度，且密封在適當容器內，並正確地標示。

vi. records are made of the results of inspection and that testing of materials, intermediate, bulk, and finished products is formally assessed against specification. Product assessment includes a review and evaluation of relevant production documentation and an assessment of deviations from specified procedures;	vi. 查核與試驗結果均應做成紀錄。原物料、半製品/中間產品、待分/包裝產品與最終產品的測試應正規地對照其規格評估之。產品評估包含相關生產文件的複審與評價以及與規定程序之偏差的評估。
vii. no batch of product is released for sale or supply prior to certification by an authorised person that it is in accordance with the requirements of the marketing authorisation;	vii. 每批產品非經被授權人證明符合上市許可的要求，不得放行以供銷售或供應。
viii. sufficient reference samples of starting materials and products are retained to permit future examination of the product if necessary and that the product is retained in its final pack unless exceptionally large packs are produced.	viii. 應保留足夠的原料與產品的對照樣品，以容許必要時該產品之未來的檢查。除非原來以異常的大包裝生產，否則，該產品應保留在其最終包裝中。
產品品質檢討（PRODUCT QUALITY REVIEW）	
1.5. Regular periodic or rolling quality reviews of all licensed medicinal products, including export only products, should be conducted with the objective of verifying the consistency of the existing process, the appropriateness of current specifications for both starting materials and finished product to highlight any trends and to identify product and process improvements.	1.5. 一切經許可的藥物產品，含外銷專用產品，其常規定期性或輪動式的品質檢討應以證實既有製程的一致性、現行規格對原料與最終產品的適當性為目標執行之，以凸顯任何趨勢並認明產品與製程之改善事項。
Such reviews should normally be conducted and documented annually, taking into account previous reviews, and should include at least:	該檢討通常應每年執行一次並加以文件化，除應參酌先前的檢討外，並至少包含：
(i) A review of starting materials and packaging materials used for the product, especially those from new sources.	(i) 用於產品之原料與包裝材料，特別是那些來自新的來源者之檢討。

(ii) A review of critical in-process controls and finished product results.	(ii) 關鍵製程中之管制與最終產品之結果的檢討。
(iii) A review of all batches that failed to meet established specification(s) and their investigation.	(iii) 不符合既定規格的一切批次及其調查之檢討。
(iv) A review of all significant deviations or non-conformances, their related investigations, and the effectiveness of resultant corrective and preventative actions taken.	(iv) 一切顯著偏離或不相符、其相關的調查，以及因而採取的改正與預防行動之效果的檢討。
(v) A review of all changes carried out to the processes or analytical methods.	(v) 對製程或分析方法所完成之一切變更的檢討。
(vi) A review of Marketing Authorisation variations submitted/granted/ refused, including those for third country (export only) dossiers.	(vi) 上市許可之變更的提交/核准/否准之檢討，包含外銷專用者之檔案在內。
(vii) A review of the results of the stability monitoring programme and any adverse trends.	(vii) 安定性監測計畫的結果與任何不良趨勢之檢討。
(viii) A review of all quality-related returns, complaints and recalls and the investigations performed at the time.	(viii) 一切與品質相關之退回、申訴與回收，以及當時所執行之調查的檢討。
(ix) A review of adequacy of any other previous product process or equipment corrective actions.	(ix) 任何其他先前產品製程或設備改正行動之適當性的檢討。
(x) For new marketing authorisations and variations to marketing authorisations, a review of post-marketing commitments.	(x) 為新上市許可及上市許可之變更所做之一個上市後許諾的檢討。
(xi) The qualification status of relevant equipment and utilities, e.g. HVAC, water, compressed gases, etc.	(xi) 相關設備與公用設施，例如，空氣調節系統（HVAC）、水、壓縮氣體等的驗證狀態。
(xii) A review of Technical Agreements to ensure that they are up to date.	(xii) 技術協議書的檢討，以確保其為最新。
The manufacturer and marketing authorisation holder, where different, should evaluate the results of this review and an assessment should be made whether corrective and preventative	製造者與上市許可持有者不同時應評估本檢討的結果，而且應評估是否應採取改正與預防行動或任何再確效。這樣的改正行動之理

action or any revalidation should be undertaken. Reasons for such corrective actions should be documented. Agreed corrective and preventative actions should be completed in a timely and effective manner. There should be management procedures for the ongoing management and review of these actions and the effectiveness of these procedures verified during self-inspection. Quality reviews may be grouped by product type, e.g. solid dosage forms, liquid dosage forms, sterile products, etc. where scientifically justified.	由應予文件化。雙方同意的改正與預防行動應以適時且有效的方式完成之。對於持續進行的管理應有管理程序，也應有這些行動及這些程序在自我查核期間經證明之效果的檢討。在符合科學正當性時，品質的檢討得按其製品類型加以分組，例如固體劑型、液體劑型、無菌製品等。
Where the marketing authorisation holder is not the manufacturer, there should be a technical agreement in place between the various parties that defines their respective responsibilities in producing the quality review. The authorised person responsible for final batch certification together with the marketing authorisation holder should ensure that the quality review is performed in a timely manner and is accurate.	在上市許可持有者不是製造者時，在各方當事人間應有一份技術協議書來界定，在產生品質檢討上其各自的職責。負責最終批次之證明的被授權人與上市許可持有者應確保品質的檢討是以適時的方式執行，而且是精確的。

第二章　人事（PERSONNEL）

原則（PRINCIPLE）	
The establishment and maintenance of a satisfactory system of quality assurance and the correct manufacture of medicinal products relies upon people. For this reason there must be sufficient qualified personnel to carry out all the tasks which are the responsibility of the manufacturer. Individual responsibilities should be clearly understood by the individuals and recorded. All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training, including hygiene instructions, relevant to their needs.	一套令人滿意之品質保證系統的建立和維持，以及藥品的正確製造，均仰賴於人。因此，藥廠有責任配置執行所有工作之足夠的合格人員。個別工作人員應清楚瞭解其負責之工作並作成紀錄。所有人員均應意識到會影響到他/她們之優良製造準則的原則，並接受初始及持續的訓練，包括與員工工作需要有關的衛生指導。
一般規定（GENERAL）	
2.1. The manufacturer should have an adequate number of personnel with the necessary qualifications and practical experience. The responsibilities placed on any one individual should not be so extensive as to present any risk to quality.	2.1. 藥廠應有適量具備必要資格及實務經驗的人員。課予每一個人的責任不應過廣，以致呈現對於品質的危險。
2.2. The manufacturer must have an organisation chart. People in responsible positions should have specific duties recorded in written job descriptions and adequate authority to carry out their responsibilities. Their duties may be delegated to designated deputies of a satisfactory qualification level. There should be no gaps or unexplained overlaps in the responsibilities of those personnel concerned with the application of Good Manufacturing Practice.	2.2. 藥廠應有組織圖。各職位的負責人應有以書面工作說明記載的特定職責，並有適當的授權，以執行其職責。其職責得請夠資格的指定代理人行之。與優良製造準則之適用有關人員的職責不應有漏洞或未經說明的重疊。

關鍵人員（KEY PERSONNEL）	
2.3. Key Personnel includes the head of Production, the head of Quality Control, and if at least one of these persons is not responsible for the release of products the authorised person(s) designated for the purpose. Normally key posts should be occupied by full-time personnel. The heads of Production and Quality Control must be independent from each other. In large organisations, it may be necessary to delegate some of the functions listed in 2.5., 2.6. and 2.7.	2.3. 關鍵人員包括生產主管、品質管制主管，以及如果這兩個人中至少有一位不負責產品之放行時，為放行之目的所指定的被授權人。重要的職位通常應由專職人員擔任。生產和品質管制部門的主管應相互獨立。大藥廠可能有必要委派人員，擔任 2.5、2.6、及 2.7 中所列之部分職務。
2.4. …	2.4. 已刪除
2.5. The head of the Production Department generally has the following responsibilities:	2.5. 生產部門的主管通常有下列職責:
i. to ensure that products are produced and stored according to the appropriate documentation in order to obtain the required quality;	i. 為獲得要求的品質，應確保依照適當的文件生產與儲存產品；
ii. to approve the instructions relating to production operations and to ensure their strict implementation;	ii. 核准與生產作業有關的指令，並確保其嚴格的實施；
iii. to ensure that the production records are evaluated and signed by an authorised person before they are sent to the Quality Control Department;	iii. 確保生產紀錄在送到品質管制部門前已由被授權人評估與簽章；
iv. to check the maintenance of his department, premises and equipment;	iv. 檢查/核對其部門、廠房及設備的維護保養；
v. to ensure that the appropriate validations are done;	v. 確保做到適當的確效；
vi. to ensure that the required initial and continuing training of his department personnel is carried out and adapted according to need.	vi. 確保其部門的人員已執行要求的起始與持續訓練，並且依需要做好調適。
2.6. The head of the Quality Control Department generally has the following responsibilities:	2.6. 品質管制部門的主管通常有下列職責:

i. to approve or reject, as he sees fit, starting materials, packaging materials, and intermediate, bulk and finished products;	i. 在他/她認為合適時核准或拒用原料、包裝材料、半製品/中間產品、待分/包裝產品和最終產品；
ii. to evaluate batch records;	ii. 評估批次紀錄；
iii. to ensure that all necessary testing is carried out;	iii. 確保已執行一切必要的試驗
iv. to approve specifications, sampling instructions, test methods and other Quality Control procedures;	iv. 核准規格、抽樣指令、試驗方法及其他品質管制程序；
v. to approve and monitor any contract analysts;	v. 核准及監測任何受託檢驗者；
vi. to check the maintenance of his department, premises and equipment;	vi. 檢查/核對其部門、廠房設施與設備的維護保養；
vii. to ensure that the appropriate validations are done;	vii. 確保已做到適當的確效；
viii. to ensure that the required initial and continuing training of his department personnel is carried out and adapted according to need. Other duties of the Quality Control Department are summarised in Chapter 6.	viii. 確保其部門的人員已經執行要求的起始與持續訓練，並依需要做好調適。品質管制部門的其他職責總括於第六章。
2.7. The heads of Production and Quality Control generally have some shared, or jointly exercised, responsibilities relating to quality. These may include, subject to any national regulations:	2.7. 生產和品質管制的主管通常有一些分擔或共同負擔之關於品質的職責。這些職責應受國家法規的規範，包括：
➢ the authorisation of written procedures and other documents, including amendments;	➢ 書載的程序和其他文件的認可，包括修訂在內；
➢ the monitoring and control of the manufacturing environment;	➢ 製造環境的監測與管制；
➢ plant hygiene;	➢ 工廠衛生；
➢ process validation;	➢ 製程確效；
➢ training;	➢ 訓練；

➢ the approval and monitoring of suppliers of materials;	➢ 原物料供應商的認可和監督；
➢ the approval and monitoring of contract manufacturers;	➢ 受託製造廠的認可和監督；
➢ the designation and monitoring of storage conditions for materials and products;	➢ 原物料和產品之儲存條件的指示和監測；
➢ the retention of records;	➢ 紀錄的保存；
➢ the monitoring of compliance with the requirements of GMP;	➢ 遵循優良製造準則之要求的監督；
➢ the inspection, investigation, and taking of samples, in order to monitor factors which may affect product quality.	➢ 樣品的查核、調查與抽取，以便監視可能會影響產品品質的因素。
訓練（TRAINING）	
2.8. The manufacturer should provide training for all the personnel whose duties take them into production areas or into control laboratories (including the technical, maintenance and cleaning personnel), and for other personnel whose activities could affect the quality of the product.	2.8. 藥廠對於因其職責會進入生產區或管制實驗室的一切人員(包括技術、維修保養及清潔人員)，以及對於其活動可能影響產品品質的其他人員，應提供訓練。
2.9. 2.9. Beside the basic training on the theory and practice of Good Manufacturing Practice, newly recruited personnel should receive training appropriate to the duties assigned to them. Continuing training should also be given, and its practical effectiveness should be periodically assessed. Training programmes should be available, approved by either the head of Production or the head of Quality Control, as appropriate. Training records should be kept.	2.9. 除了有關優良製造準則的理論與實務的基本訓練之外，新招募的人員應接受適合於其指定之職責的適當訓練。同時也應提供後續的訓練，並應對訓練的實際效果定期予以評估。應有視情況經生產部門或品質管制部門的主管批准的訓練計畫。訓練紀錄應予保存。
2.10. Personnel working in areas where contamination is a hazard, e.g. clean areas or areas where highly active, toxic, infectious or sensitising materials are handled, should be given specific training.	2.10. 對於在一有污染即產生危險之區域中工作的人員，例如在潔淨區或在處理高生理活性的、毒性的、傳染性的或致敏性的物質之區域中工作的人員，應給予特別的訓練。

2.11. Visitors or untrained personnel should, preferably, not be taken into the production and Quality Control areas. If this is unavoidable, they should be given information in advance, particularly about personal hygiene and the prescribed protective clothing. They should be closely supervised.	2.11. 參觀人員和未受過訓練的人員，應最好不要帶入生產區和品質管制區中。無法避免時，應事先提供資訊給他/她們，特別是關於個人衛生及規定的防護裝。對他/她們應予密切監督。
2.12. The concept of Quality Assurance and all the measures capable of improving its understanding and implementation should be fully discussed during the training sessions.	2.12. 在訓練期間，應充分討論品質保證的概念和一切能夠增進其理解與施行的措施。
個人衛生（PERSONAL HYGIENE）	
2.13. Detailed hygiene programmes should be established and adapted to the different needs within the factory. They should include procedures relating to the health, hygiene practices and clothing of personnel. These procedures should be understood and followed in a very strict way by every person whose duties take him into the production and control areas. Hygiene programmes should be promoted by management and widely discussed during training sessions.	2.13. 詳細的衛生計畫應予建立，並針對工廠內的不同需求調適之。該計畫應包括與人員健康、衛生習慣及服裝等有關的程序。因其職責而會進入生產區及管制區的每一個人，皆應了解這些程序，並以非常嚴格的方式遵守之。管理階層應推動衛生計畫並在訓練期間予以廣泛討論。
2.14. All personnel should receive medical examination upon recruitment. It must be the manufacturer's responsibility that there are instructions ensuring that health conditions that can be of relevance to the quality of products come to the manufacturer's knowledge. After the first medical examination, examinations should be carried out when necessary for the work and personal health.	2.14. 在雇用時，一切人員皆應接受體檢。藥廠有職責發佈指令，以確保人員與產品品質可能有關之健康狀況會為藥廠所知。在第一次體檢後，因工作和人員健康有必要時，還應為體檢。
2.15. Steps should be taken to ensure as far as is practicable that no person affected by an infectious disease or having open lesions on the exposed surface of the body is engaged in the manufacture of medicinal products.	2.15. 應儘可能採取步驟，確保不會有受到傳染性疾病感染的人或在暴露的身體表面上有開放性傷口的人從事於藥品的製造。

2.16. Every person entering the manufacturing areas should wear protective garments appropriate to the operations to be carried out.	2.16. 進入製造區的每一個人均應穿戴適合於其所要執行之作業的防護裝。
2.17. Eating, drinking, chewing or smoking, or the storage of food, drink, smoking materials or personal medication in the production and storage areas should be prohibited. In general, any unhygienic practice within the manufacturing areas or in any other area where the product might be adversely affected, should be forbidden.	2.17. 在生產區及儲存區內應不得/禁止飲食、嚼或吸煙，或是儲存食物、飲料、煙類或是個人的醫療用品。在製造區內或在產品可能會受到不良影響的任何其他區域中，任何不合衛生的行為原則上均應予禁止。
2.18. Direct contact should be avoided between the operator's hands and the exposed product as well as with any part of the equipment that comes into contact with the products.	2.18. 工作人員應避免其雙手直接接觸暴露的產品以及會與產品接觸之設備的任何部份。
2.19. Personnel should be instructed to use the hand-washing facilities.	2.19. 應教導工作人員使用洗手設施。
2.20. Any specific requirements for the manufacture of special groups of products, for example sterile preparations, are covered in the Supplementary Guidelines.	2.20. 為諸如無菌製劑之特別產品組別的製造，其任何特別要求收載於分則中。

第三章　廠房設施與設備（PREMISES AND EQUIPMENT）

原則（PRINCIPLE）	
Premises and equipment must be located, designed, constructed, adapted and maintained to suit the operations to be carried out. Their layout and design must aim to minimise the risk of errors and permit effective cleaning and maintenance in order to avoid cross-contamination, build up of dust or dirt and, in general, any adverse effect on the quality of products.	廠房設施和設備的定位、設計、建造、調適及維護皆應適合於其所要執行的作業。其配置與設計應以將產生錯誤的風險降到最低，並容許有效的清潔和維護保養，以避免交叉污染、聚積粉塵或污垢，總之應以避免對產品品質有任何不利影響為目標。
廠房設施（PREMISES）	
一般規定（General）	
3.1. Premises should be situated in an environment which, when considered together with measures to protect the manufacture, presents minimal risk of causing contamination of materials or products.	3.1. 當與保護製造的措施一起考慮時，廠房應座落在引起原物料或產品之污染呈現出最低風險的環境中。
3.2. Premises should be carefully maintained, ensuring that repair and maintenance operations do not present any hazard to the quality of products. They should be cleaned and, where applicable, disinfected according to detailed written procedures.	3.2. 廠房應謹慎維護，以確保其修理和維護作業不會危害於產品品質。廠房應予清潔，適當時並依詳細的書載程序消毒之。
3.3. Lighting, temperature, humidity and ventilation should be appropriate and such that they do not adversely affect, directly or indirectly, either the medicinal products during their manufacture and storage, or the accurate functioning of equipment.	3.3. 照明、溫度、濕度和通風均應適當，並使其不會直接或間接地不利影響在其製造及儲存中的藥品，或設備的正確功能。
3.4. Premises should be designed and equipped so as to afford maximum protection against the entry of insects or other animals.	3.4. 廠房應以提供防止昆蟲或其他動物的入侵之最大的保護為目的設計與裝配之。
3.5. Steps should be taken in order to prevent the entry of unauthorised people. Production, storage and quality control areas should not be used as a right of way by personnel who do not work in them.	3.5. 為防止未被授權的人員進入廠房，應採取步驟。生產區、儲存區及品質管制區不得做為非該區工作人員的通路使用。

生產區（**Production Area**）	
3.6. In order to minimise the risk of a serious medical hazard due to cross contamination, dedicated and self-contained facilities must be available for the production of particular medicinal products, such as highly sensitising materials (e.g. penicillins) or biological preparations (e.g. from live micro-organisms). The production of certain additional products, such as certain antibiotics, certain hormones, certain cytotoxics, certain highly active drugs and non-medicinal products should not be conducted in the same facilities. For those products, in exceptional cases, the principle of campaign working in the same facilities can be accepted provided that specific precautions are taken and the necessary validations are made. The manufacture of technical poisons, such as pesticides and herbicides, should not be allowed in premises used for the manufacture of medicinal products.	3.6. 為使因交叉污染所引起之嚴重醫療傷害的風險降到最低，對於一些特殊藥品的生產，例如高致敏性物質（如：青黴素類）或生物性製劑（如：來自活的微生物），應有專用且自足圍堵的設施；尚有一些產品，例如某些抗生素、某些荷爾蒙、某些細胞毒類、某些高活性藥物及非藥品的生產不得在同一設施中為之。如採取特別的預防措施，並為必要的確效時，在例外的情形，可以接受在同一設施中的時段切換生產原則。工業毒物諸如殺蟲劑和除草劑不得允許在使用於藥品之製造的廠房中為之。
3.7. Premises should preferably be laid out in such a way as to allow the production to take place in areas connected in a logical order corresponding to the sequence of the operations and to the requisite cleanliness levels.	3.7. 廠房最好是配合作業順序及必要的清淨度水準配置之，以容許在一個邏輯次序相連的區域中進行生產。
3.8. The adequacy of the working and in-process storage space should permit the orderly and logical positioning of equipment and materials so as to minimise the risk of confusion between different medicinal products or their components, to avoid cross-contamination and to minimise the risk of omission or wrong application of any of the manufacturing or control steps.	3.8. 作業空間與製程中儲存空間的適當性，應允許設備與原物料有條理且合乎邏輯的放置，以便使不同藥品或其組成物/組件間之混淆風險降到最低，避免交叉污染，並使任何一個製造或管制步驟的遺漏或是錯誤應用的風險降到最低。

3.9. Where starting and primary packaging materials, intermediate or bulk products are exposed to the environment, interior surfaces (walls, floors and ceilings) should be smooth, free from cracks and open joints, and should not shed particulate matter and should permit easy and effective cleaning and, if necessary, disinfection.	3.9. 在原料與直接包裝材料、半製品/中間產品或待分/包裝產品暴露的環境，其內部表面(牆壁、地板及天花板)應該平滑、沒有裂縫和沒有開口的接頭，且不得脫落微粒物質，還應容易且有效地清潔，如有必要，還可消毒。
3.10. Pipe work, light fittings, ventilation points and other services should be designed and sited to avoid the creation of recesses which are difficult to clean. As far as possible, for maintenance purposes, they should be accessible from outside the manufacturing areas.	3.10. 管路工程、照明裝置、通氣口以及其他設施，應如此設計與定位，以避免產生難以清潔的凹處。為維護保養之目的，應儘可能可從製造區外進行。
3.11. Drains should be of adequate size, and have trapped gullies. Open channels should be avoided where possible, but if necessary, they should be shallow to facilitate cleaning and disinfection.	3.11. 排水管應有合適的大小，並備有捕集裝置的溝渠。如有可能，應盡量避免開放式的管路，但不得已時，該管路應為淺溝，以利清潔與消毒。
3.12. Production areas should be effectively ventilated, with air control facilities (including temperature and, where necessary, humidity and filtration) appropriate both to the products handled, to the operations undertaken within them and to the external environment.	3.12. 生產區應有效通風，並備有適合於所處理的產品、在該區域內所從事的作業，以及外在環境等的空氣管控設施（包含溫度，必要時包含濕度與過濾）。
3.13. Weighing of starting materials usually should be carried out in a separate weighing room designed for that use.	3.13. 原料的秤重，通常應在專為該用途所設計之一間隔離的秤重室內為之。
3.14. In cases where dust is generated (e.g. during sampling, weighing, mixing and processing operations, packaging of dry products), specific provisions should be taken to avoid cross-contamination and facilitate cleaning.	3.14. 在會產生粉塵的情況中(例如：在抽樣、秤重、混合及操作作業、乾燥產品的分/包裝期間)，應採取特別的防備，以避免交叉污染及以利清潔。
3.15. Premises for the packaging of medicinal products should be specifically designed and laid out so as to avoid mix-ups or cross-contamination.	3.15. 藥品分/包裝的廠房，應特別設計與布置，以避免混雜或交叉污染。

3.16. Productions areas should be well lit, particularly where visual on-line controls are carried out.	3.16. 生產區應有良好的照明，特別是在執行線上目視管制的場所。
3.17. In-process controls may be carried out within the production area provided they do not carry any risk for the production.	3.17. 製程中管制不會對生產帶來任何危險者，可在生產區內執行之。
儲存區（Storage Areas）	
3.18. Storage areas should be of sufficient capacity to allow orderly storage of the various categories of materials and products: starting and packaging materials, intermediate, bulk and finished products, products in quarantine, released, rejected, returned or recalled.	3.18. 儲存區應有足夠的容量，以容許各種類別的原物料及產品之有條理的儲存，包括：原料及包裝材料、半製品/中間產品、待分/包裝產品及最終產品、待驗產品、放行產品、拒用產品、退回產品或回收產品等。
3.19. Storage areas should be designed or adapted to ensure good storage conditions. In particular, they should be clean and dry and maintained within acceptable temperature limits. Where special storage conditions are required (e.g. temperature, humidity) these should be provided, checked and monitored.	3.19. 儲存區應設計或調適來確保優良的儲存條件。特別是儲存區應是潔淨與乾燥，並維持在可接受的溫度範圍內。要求有特別的儲存條件(如溫度及濕度)時，應提供這些儲存場所，並加以檢查/核對與監測。
3.20. Receiving and dispatch bays should protect materials and products from the weather. Receptions areas should be designed and equipped to allow containers of incoming materials to be cleaned where necessary before storage.	3.20. 收貨區和出貨區應保護原物料和產品免於受到天氣的影響。收貨區應加以設計並裝備，以容許必要時能夠在儲存之前清潔進廠原物料的容器。
3.21. Where quarantine status is ensured by storage in separate areas, these areas must be clearly marked and their access restricted to authorised personnel. Any system replacing the physical quarantine should give equivalent security.	3.21. 藉由儲存於分開的區域來確保隔離狀態者，該區域應標識清楚，其進入應限於被授權人員。任何取代該實體隔離的系統，應提供同等的安全。
3.22. There should normally be a separate sampling area for starting materials. If sampling is performed in the storage area, it should be conducted in such a way as to prevent contamination or cross-contamination.	3.22. 原料通常應有隔離的抽樣區域。在儲存區內執行抽樣者，應以可以防止污染或交叉污染的方式執行之。

3.23. Segregated areas should be provided for the storage of rejected, recalled or returned materials or products.	3.23. 對於拒用、回收或退回的原物料或產品之儲存，應提供隔離的區域。
3.24. Highly active materials or products should be stored in safe and secure areas.	3.24. 高活性的物質或產品應儲存於安全且牢靠的區域中。
3.25. Printed packaging materials are considered critical to the conformity of the medicinal products and special attention should be paid to the safe and secure storage of these materials.	3.25. 印刷的包裝材料對於藥品的符合性是很重要的，所以應當特別注意這些包裝材料之安全和牢靠的儲存。
品質管制區（Quality Control Areas）	
3.26. Normally, Quality Control laboratories should be separated from production areas. This is particularly important for laboratories for the control of biological, microbiological and radioisotopes, which should also be separated from each other.	3.26. 通常，品質管制實驗室應與生產區隔離。這對生物學的、微生物學的和放射性同位素之管制的實驗室特別重要。這些實驗室也應當互相隔離。
3.27. Control laboratories should be designed to suit the operations to be carried out in them. Sufficient space should be given to avoid mix-ups and cross contamination. There should be adequate suitable storage space for samples and records.	3.27. 管制實驗室應設計成適合於要在這些實驗室內執行的作業，並應給予足夠空間，以防止混雜及交叉污染。對於樣品與紀錄也應有足夠的適當儲存空間。
3.28. Separate rooms may be necessary to protect sensitive instruments from vibration, electrical interference, humidity, etc.	3.28. 隔離的儀器室可能是必需的，以保護靈敏的儀器設備免於受到振動、電子干擾、濕氣等的影響。
3.29. Special requirements are needed in laboratories handling particular substances, such as biological or radioactive samples.	3.29. 處理特別物質，例如生物樣品或放射性樣品的實驗室，需要有特別的要求。
附屬區域（Ancillary Areas）	
3.30. Rest and refreshment rooms should be separate from other areas.	3.30. 休息室與餐廳應與其他區域隔離。
3.31. Facilities for changing clothes, and for washing and toilet purposes should be easily accessible and appropriate for the number of users. Toilets should not directly communicate with production or storage areas.	3.31. 更衣、洗滌和盥洗目的之設施應便於使用並適合使用人數。廁所與生產區或儲存區不得直接相通。

3.32. Maintenance workshops should as far as possible be separated from production areas. Whenever parts and tools are stored in the production area, they should be kept in rooms or lockers reserved for that use.	3.32. 維修保養工場應儘可能與生產區隔離。在生產區儲存零件和工具者，應儲存在其專用室或專用櫃中。
3.33. Animal houses should be well isolated from other areas, with separate entrance (animal access) and air handling facilities.	3.33. 動物室應與其他區域妥善隔離，並有分別的入口（動物的進出口）及空調處理設施。
設備（EQUIPMENT）	
3.34. Manufacturing equipment should be designed, located and maintained to suit its intended purpose.	3.34. 製造設備應設計、配置及維護保養，以適合其預定目的。
3.35. Repair and maintenance operations should not present any hazard to the quality of the products.	3.35. 修理及維修保養作業不得對產品的品質呈現任何危險。
3.36. Manufacturing equipment should be designed so that it can be easily and thoroughly cleaned. It should be cleaned according to detailed and written procedures and stored only in a clean and dry condition.	3.36. 製造設備應如是設計，以使其能夠容易且徹底地清洗。該設備應依詳細的書載程序清洗，並只儲存在潔淨且乾燥的條件中。
3.37. Washing and cleaning equipment should be chosen and used in order not to be a source of contamination.	3.37. 洗滌及清潔設備應加以選擇與使用，以使其不會成為污染的來源。
3.38. 3.38. Equipment should be installed in such a way as to prevent any risk of error or of contamination.	3.38. 設備應以適當的方式安裝，以防止任何錯誤或污染的風險。
3.39. Production equipment should not present any hazard to the products. The parts of the production equipment that come into contact with the product must not be reactive, additive or absorptive to such an extent that it will affect the quality of the product and thus present any hazard.	3.39. 生產設備不得呈現對產品有任何危險。生產設備與產品接觸的部分之反應性、加成性或吸附性不得高到足以影響產品的品質，從而呈現任何危險。
3.40. Balances and measuring equipment of an appropriate range and precision should be available for production and control operations.	3.40. 應備有適當測量範圍與精密度的天平與量測設備，以供生產與管制作業使用。

3.41. Measuring, weighing, recording and control equipment should be calibrated and checked at defined intervals by appropriate methods. Adequate records of such tests should be maintained.	3.41. 量测、秤重、記錄及管制設備應在界定的時間間隔內，使用適當的方法校正並檢查/核對之。這些檢測的適當紀錄應予保存。
3.42. Fixed pipework should be clearly labelled to indicate the contents and, where applicable, the direction of flow.	3.42. 固定的管線應清楚標示，以標識其內容物，可行時，也應標識內容物流動的方向。
3.43. Distilled, deionized and, where appropriate, other water pipes should be sanitised according to written procedures that detail the action limits for microbiological contamination and the measures to be taken.	3.43. 蒸餾水、去離子水及合適時其他用水配管應依書載程序執行滅菌處理。該文件應詳載微生物污染的行動限量及應採取的措施。
3.44. Defective equipment should, if possible, be removed from production and quality control areas, or at least be clearly labeled as defective.	3.44. 有缺陷的設備，如果可能，應從生產區和品質管制區內搬出，或至少清楚標示其為“有缺陷的設備”。

第四章　文件（DOCUMENTATION）

原則（PRINCIPLE）	
Good documentation constitutes an essential part of the quality assurance system. Clearly written documentation prevents errors from spoken communication and permits tracing of batch history. Specifications, Manufacturing Formulae and instructions, procedures, and records must be free from errors and available in writing. The legibility of documents is of paramount importance.	優良的文件構成品質保證系統之不可缺的部分。清楚的書面文件避免來自於口頭溝通的誤解，並且容許批次歷史的追蹤。規格、製造配方與指令、程序，以及紀錄必須免於錯誤，並且可取得其書面資料。這些文件的易讀性極為重要。
一般規定（GENERAL）	
4.1. Specifications describe in detail the requirements with which the products or materials used or obtained during manufacture have to conform. They serve as a basis for quality evaluation. Manufacturing Formulae, Processing and Packaging Instructions state all the starting materials used and lay down all processing and packaging operations. Procedures give directions for performing certain operations e.g. cleaning, clothing, environmental control, sampling, testing, equipment operations. Records provide a history of each batch of product, including its distribution, and also of all other relevant circumstances pertinent for the quality of the final product.	4.1. 規格詳細描述在製造期間使用的或獲得的產品或原物料應符合的要求。規格用為品質評價的基礎。製造配方、操作程序及分/包裝指令載明使用的全部原料，並明訂一切操作程序及分/包裝作業。程序提供執行某些作業的指引，例如清潔、衣著、環境控制、抽樣、測試、及設備的操作等。紀錄提供每批產品的歷史，包括其運銷，以及其他一切與最終產品之品質有關的細節。
4.2. Documents should be designed, prepared, reviewed and distributed with care. They should comply with the relevant parts of the manufacturing and marketing authorisation dossiers.	4.2. 文件應謹慎設計、制訂、審查/複核與分發，並應遵守製造及上市許可文件中之相關部分。
4.3. Documents should be approved, signed and dated by appropriate and authorised persons.	4.3. 文件應由適當之被授權人核定、簽章並註明日期。

4.4. Documents should have unambiguous contents; title, nature and purpose should be clearly stated. They should be laid out in an orderly fashion and be easy to check. Reproduced documents should be clear and legible. The reproduction of working documents from master documents must not allow any error to be introduced through the reproduction process.	4.4. 文件應有明確的內容；其標題、性質及目的應清楚說明，並以整齊的方式編排，且易於查核/核對。複製的文件應清楚易讀。由正本複製的工作文件不得有由於複製過程而導入的任何錯誤。
4.5. Documents should be regularly reviewed and kept up-to-date. When a document has been revised, systems should be operated to prevent inadvertent use of superseded documents.	4.5. 文件應定期再予檢查並不斷更新。當一份文件已經過修訂，則應運作系統，以防止廢棄文件粗心再被使用。
4.6. Documents should not be hand-written; although, where documents require the entry of data, these entries may be made in clear, legible, indelible handwriting. Sufficient space should be provided for such entries.	4.6. 在文件需要填入數據時，雖然其填入得以清晰、可讀且擦不掉的手筆為之，但文件本身不得用手寫。應有足夠的空間供此種數據的填入。
4.7. Any alteration made to the entry on a document 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.	4.7. 在一份文件上對於該填入項目所做的任何更改應予簽章並註明日期；該更改應允許原來資訊的讀取。在合適時，該更改的理由應記錄之。
4.8. The records should be made or completed at the time each action is taken and in such a way that all significant activities concerning the manufacture of medicinal products are traceable. They should be retained for at least one year after the expiry date of the finished product.	4.8. 在採取每一項行動時，就應從事或完成紀錄；依此方法，使與藥品的製造有關的一切重要活動都是可以追蹤的。這些紀錄應保存至最終產品的末效日期後至少一年。
4.9. Data may be recorded by electronic data processing systems, photographic or other reliable means, but detailed procedures relating to the system in use should be available and the accuracy of the records should be checked. If documentation is handled by electronic data processing methods, only authorised persons should be able to enter or modify data in the	4.9. 數據可用電子數據處理系統、照相或其他可靠的方法記錄之，但應可取得關於使用中之系統的詳細程序，而且這些紀錄的精確性應予查核/核對。文件化係由電子數據處理系統處理者，只有被授權人才可以進入或更改電腦中的數據，並應有修改和刪除的紀錄。進入系統應以

computer and there should be a record of changes and deletions; access should be restricted by passwords or other means and the result of entry of critical data should be independently checked. Batch records electronically stored should be protected by back-up transfer on magnetic tape, microfilm, paper or other means. It is particularly important that the data are readily available throughout the period of retention.	密碼或其他方法限制之；重要數據之輸入的結果應有獨立的查核/核對。用電子方法儲存的批次紀錄應以備份轉錄在磁帶、微縮軟片、紙張上或以其他方法保護之。在保存期間的全程，可以隨時取得數據是特別重要的。
要求的文件（DOCUMENTS REQUIRED）	
規格（Specifications）	
4.10. There should be appropriately authorised and dated specifications for starting and packaging materials, and finished products; where appropriate, they should be also available for intermediate or bulk products.	4.10. 對於原料、包裝材料和最終產品，應有適當經核准且註明日期的規格；合適時，對於半製品/中間產品或待分/包裝產品，也應有其規格。
原料及包裝材料的規格（Specifications for starting and packaging materials）	
4.11. Specifications for starting and primary or printed packaging materials should include, if applicable:	4.11. 原料及直接包裝或印刷的包裝材料之規格，如果可行，應包括:
a) description of the materials, including:	a) 原物料的描述，包括：
➢ . the designated name and the internal code reference;	➢ 指定的名稱和內部的參考代碼；
➢ . the reference, if any, to a pharmacopoeial monograph;	➢ 藥典專論的參考資料(如有時)；
➢ . the approved suppliers and, if possible, the original producer of the products;	➢ 產品之認可的供應商，及其原始的生產者(如可能時)；
➢ . a specimen of printed materials;	➢ 印刷材料的樣本；
b) directions for sampling and testing or reference to procedures;	b) 抽樣、測試的指示或參照的程序；
c) qualitative and quantitative requirements with acceptance limits;	c) 具有合格標準範圍之定性和定量的要求；
d) storage conditions and precautions;	d) 儲存的條件及注意事項；
e) the maximum period of storage before re-examination.	e) 再驗前的最長儲存期間。

半製品/中間產品及待分/包裝產品的規格（Specifications for intermediate and bulk products）	
4.12. Specifications for intermediate and bulk products should be available if these are purchased or dispatched, or if data obtained from intermediate products are used for the evaluation of the finished product. The specifications should be similar to specifications for starting materials or for finished products, as appropriate.	4.12. 在採購或發送半製品/中間產品和待分/包裝產品時，或從半製品/中間產品取得的數據使用於最終產品的評價時，應有半製品/中間產品與待分/包裝產品的規格。合適時，這些規格應類似於原料或最終產品的規格。
最終產品的規格（Specifications for finished products）	
4.13. Specifications for finished products should include:	4.13. 最終產品的規格應包括:
a) the designated name of the product and the code reference where applicable;	a) 產品之指定名稱及其參考代碼(可行時)；
b) the formula or a reference to;	b) 配方或參考資料；
c) a description of the pharmaceutical form and package details;	c) 產品劑型及包裝細節的描述；
d) directions for sampling and testing or a reference to procedures;	d) 抽樣和測試的指示或參考的程序；
e) the qualitative and quantitative requirements, with the acceptance limits;	e) 具有合格標準範圍之定性及定量的要求；
f) the storage conditions and any special handling precautions, where applicable;	f) 儲存條件及任何特別處理的注意事項(可行時)；
g) the shelf-life.	g) 架儲期；
製造配方及操作指令（MANUFACTURING FORMULA AND PROCESSING INSTRUCTIONS）	
Formally authorised Manufacturing Formula and Processing Instructions should exist for each product and batch size to be manufactured. They are often combined in one document.	所要製造之每一產品及其批量應有經正式批准的製造配方與操作指令。這些常常合併在一份文件中。
4.14. The Manufacturing Formula should include:	4.14. 製造配方應包括:
a) the name of the product, with a product reference code relating to its specification;	a) 產品的名稱及其規格有關的產品參考代碼；

b) description of the pharmaceutical form, strength of the product and batch size;	b) 產品劑型、含量以及批量的描述；
c) a list of all starting materials to be used, with the amount of each, described using the designated name and a reference which is unique to that material; mention should be made of any substance that may disappear in the course of processing;	c) 將使用之一切原料及其用量的清單，並描述其指定的名稱及專有的代碼；敘明在操作過程中可能喪失之任何物質；
d) a statement of the expected final yield with the acceptable limits, and of relevant intermediate yields, where applicable.	d) 說明預期最終產率/產量及其合格標準的範圍，以及相關半製品/中間產品產率/產量(可行時)。
4.15. The Processing Instructions should include：	4.15. 操作指令應包括：
a) statement of the processing location and the principal equipment to be used;	a) 作業場所及主要設備的說明；
b) the methods, or reference to the methods, to be used for preparing the critical equipment (e.g. cleaning, assembling, calibrating, sterilising);	b) 準備關鍵設備所要使用的方法或該方法的參考資料(例如清潔、組裝、校正、滅菌)；
c) detailed stepwise processing instructions (e.g. checks on materials, pretreatments, sequence for adding materials, mixing times, temperatures);	c) 詳細之逐步操作的指令(例如原物料的檢查/核對、前處理、添加原料的順序、混合時間、溫度)；
d) the instructions for any in-process controls with their limits;	d) 任何製程中管制的指令及其界限；
e) where necessary, the requirements for bulk storage of the products; including the container, labelling and special storage conditions where applicable;	e) 必要時，對於產品之待分/包裝儲存的要求；可行時，包括其容器、標示及特別的儲存條件；
f) any special precautions to be observed.	f) 應遵守的任何特別注意事項。
分/包裝指令（PACKAGING INSTRUCTIONS）	
4.16. There should be formally authorised Packaging Instructions for each product for pack size and type. These should normally include, or have a reference to, the following：	4.16. 對於每種產品的包裝量與形式都應有一個經正式核准的分/包裝指令。這些分/包裝指令通常應包括或提及下列項目：
a) name of the product;	a) 產品名稱；

b) description of its pharmaceutical form, and strength where applicable;	b) 劑型，及其含量的描述(可行時)；
c) the pack size expressed in terms of the number, weight or volume of the product in the final container;	c) 包裝量以產品在最終容器的數量、重量或容量來表示之；
d) a complete list of all the packaging materials required for a standard batch size, including quantities, sizes and types, with the code or reference number relating to the specifications of each packaging material;	d) 一個標準批量需要之全部包裝材料的清單，包括其數量、尺寸和型式及每一種包裝材料之規格有關的代碼或參考號碼；
e) where appropriate, an example or reproduction of the relevant printed packaging materials, and specimens indicating where to apply batch number references, and shelf-life of the product;	e) 相關經印刷之包裝材料的實例或複製品(合適時)，以及標識在何處印上產品之批號參考資料和架儲期的樣本；
f) special precautions to be observed, including a careful examination of the area and equipment in order to ascertain the line clearance before operations begin;	f) 要遵行的特別注意事項，包括作業區與設備的小心檢查，以確實探知在作業開始前已完成分/包裝線的清線工作；
g) a description of the packaging operation, including any significant subsidiary operations, and equipment to be used;	g) 分/包裝作業之描述，包括任何重要的輔助作業，以及要使用的設備；
h) details of in-process controls with instructions for sampling and acceptance limits.	h) 具有抽樣及合格標準範圍指令之製程中管制的細節；
批次製造紀錄（BATCH PROCESSING RECORDS）	
4.17. A Batch Processing Record should be kept for each batch processed. It should be based on the relevant parts of the currently approved Manufacturing Formula and Processing Instructions. The method of preparation of such records should be designed to avoid transcription errors. The record should carry the number of the batch being manufactured.	4.17. 就每一製造的批次應保存一份批次製造紀錄。這應根據現行認可的製造配方及操作指令的相關部分。這些紀錄的製作方法應加以設計，以避免抄錄錯誤。該紀錄應帶有該製造批次的批號。

Before any processing begins, there should be recorded checks that the equipment and work station are clear of previous products, documents or materials not required for the planned process, and that equipment is clean and suitable for use.	在任何操作開始前，應有檢查/核對紀錄，包括設備和工作場所無先前的產品、也無本製程不要求的文件或原物料，以及該設備是潔淨且適合使用。
During processing, the following information should be recorded at the time each action is taken and, after completion, the record should be dated and signed in agreement by the person responsible for the processing operations :	操作期間，下列資訊應在採取每一個行動時（由操作者）記錄之，且在完成後，該紀錄應由該操作作業負責人同意後註明日期並簽章：
a) the name of the product;	a) 該產品的名稱；
b) dates and times of commencement, of significant intermediate stages and of completion of production;	b) 生產之開始、重要中間階段及完成的日期和時間；
c) name of the person responsible for each stage of production;	c) 負責每一個生產階段之人的姓名；
d) initials of the operator of different significant steps of production and, where appropriate, of the person who checked each of these operations (e.g. weighing);	d) 不同的重要生產步驟之作業人員的簽名，以及合適時，這些作業(如秤重)之每一步驟的核對人員之簽名；
e) the batch number and/or analytical control number as well as the quantities of each starting material actually weighed (including the batch number and amount of any recovered or reprocessed material added);	e) 實際秤取之每一原料的批號及/或分析管制的號碼以及重量(包括添加之任何收回或重製/重處理的原料之批號及重量)；
f) any relevant processing operation or event and major equipment used;	f) 任何相關之操作作業或事件及使用之主要的設備；
g) a record of the in-process controls and the initials of the person(s) carrying them out, and the results obtained;	g) 製程中管制的紀錄和執行該管制之人員的簽名，以及取得的結果；
h) the amount of product yield obtained at different and pertinent stages of manufacture;	h) 在製造的不同階段以及相關階段所獲得的產品產率/產量；

i) notes on special problems including details, with signed authorisation for any deviation from the Manufacturing Formula and Processing Instructions.	i) 與製造配方及操作指令有任何偏差之特別問題，包含簽章認可之詳細記錄
批次分/包裝紀錄（BATCH PACKAGING RECORDS）	
4.18. A Batch Packaging Record should be kept for each batch or part batch processed. It should be based on the relevant parts of the Packaging Instructions and the method of preparation of such records should be designed to avoid transcription errors. The record should carry the batch number and the quantity of bulk product to be packed, as well as the batch number and the planned quantity of finished product that will be obtained.	4.18. 就每一批次或部分批次的操作皆應保存一份批次分/包裝紀錄。這應根據分/包裝指令的相關部分製作，且這些紀錄的製作方法應加以設計，以避免抄錄錯誤。分/包裝紀錄應有待分/包裝之分/包裝產品的批號和數量，以及將可獲得之最終產品的批號與計劃的數量。
Before any packaging operation begins, there should be recorded checks that the equipment and work station are clear of previous products, documents or materials not required for the planned packaging operations, and that equipment is clean and suitable for use.	在任何分/包裝作業開始前，應製作檢查/核對紀錄，包括設備和工作場所無本分/包裝作業計畫不需要之先前的產品、文件或原物料，以及該設備是潔淨且適合使用。
The following information should be entered at the time each action is taken and, after completion, the record should be dated and signed in agreement by the person(s) responsible for the packaging operations:	下列資訊應在採取每一個行動時（由操作者）記錄之，且在其完成後，該紀錄應由分/包裝作業負責人同意後註明日期並予簽章：
a) the name of the product;	a) 產品名稱；
b) the date(s) and times of the packaging operations;	b) 分/包裝作業的日期和時間；
c) the name of the responsible person carrying out the packaging operation;	c) 負責執行分/包裝作業人員的姓名；
d) the initials of the operators of the different significant steps;	d) 不同重要步驟之作業人員的簽名；
e) records of checks for identity and conformity with the Packaging Instructions including the results of in-process controls;	e) 分/包裝指令之識別與符合性的核對紀錄，包含製程中管制的結果在內；

f) details of the packaging operations carried out, including references to equipment and the packaging lines used;	f) 執行之分/包裝作業的細節，包含使用的設備與分/包裝線的參考資料；
g) whenever possible, samples of printed packaging materials used, including specimens of the batch coding, expiry dating and any additional overprinting;	g) 每逢可能時，使用之印刷的包裝材料之樣品，包括批次代碼、末效日期及任何加印的樣本；
h) notes on any special problems or unusual events including details with signed authorisation for any deviation from the Manufacturing Formula and Processing Instructions;	h) 就任何特殊問題或異常事件的記錄，包含與製造配方及操作指令有任何偏差而經簽章認可的細節；
i) the quantities and reference number or identification of all printed packaging materials and bulk product issued, used, destroyed or returned to stock and the quantities of obtained product, in order to provide for an adequate reconciliation.	i) 發出、使用、銷毀或退回庫存之全部印刷的包裝材料和待分/包裝產品的數量與參考號碼或其鑑識，及所得之產品數量，以便提供一個適當的數量調和。
程序與紀錄（PROCEDURES AND RECORDS）	
接收（Receipt）	
4.19. There should be written procedures and records for the receipt of each delivery of each starting and primary and printed packaging material.	4.19. 每一種原料、主要的包裝材料和印刷的包裝材料之每次交貨的受領皆應有書載的程序與紀錄。
4.20. The records of the receipts should include:	4.20. 接收紀錄應包括:
a) the name of the material on the delivery note and the containers;	a) 在送貨單和容器上的原物料名稱；
b) the "in-house" name and/or code of material (if different from a);	b) 原物料之“廠內”的名稱及/或代碼(如異於 a 時)；
c) date of receipt;	c) 接收日期；
d) supplier's name and, if possible, manufacturer's name;	d) 供應商的名稱，及製造廠的名稱(如有可能)；
e) manufacturer's batch or reference number;	e) 製造廠的批號或參考號碼；
f) total quantity, and number of containers received;	f) 接收的總量及容器的數目；
g) the batch number assigned after receipt;	g) 接收後指定的批號；

h) any relevant comment (e.g. state of the containers).	h) 任何相關的加註 (例如：容器的狀態)。
4.21. There should be written procedures for the internal labelling, quarantine and storage of starting materials, packaging materials and other materials, as appropriate.	4.21. 為原料、包裝材料及合適時，其他原材料的廠內標示、隔離和儲存應有書載的程序。
抽樣（Sampling）	
4.22. There should be written procedures for sampling, which include the person(s) authorised to take samples, the methods and equipment to be used, the amounts to be taken and any precautions to be observed to avoid contamination of the material or any deterioration in its quality (see Chapter 6, Item 13).	4.22. 為抽樣，應有書載的程序。該程序包括被授權抽樣的人、要使用的方法和設備、要抽取的樣品量與應遵守的預防措施，以避免原物料的污染或其品質的降低(請參見第六章，第十三項)
試驗（Testing）	
4.23. There should be written procedures for testing materials and products at different stages of manufacture, describing the methods and equipment to be used. The tests performed should be recorded (see Chapter 6, Item 17).	4.23. 為在不同製造階段測試原物料及產品，應有書載的程序。該程序描述要使用的方法及設備。執行的試驗應加以記錄(請參見第六章，第十七項)。
其他（Other）	
4.24. Written release and rejection procedures should be available for materials and products, and in particular for the release for sale of the finished product by the authorised person(s) designated for the purpose.	4.24. 為原物料及產品之放行及拒用，特別是為最終產品之銷售而由為該目的指定之被授權人放行的情形，應有書載的程序。
4.25. Records should be maintained of the distribution of each batch of a product in order to facilitate the recall of the batch if necessary (see Chapter 8).	4.25. 應保存每一產品之每批運銷的紀錄，以便利該批次在必要時的回收 (請參見第八章)。
4.26. There should be written procedures and the associated records of actions taken or conclusions reached, where appropriate, for:	4.26. 對下列事項應有書載程序及採取之行動或合適時，其達成之結論的相關紀錄：
➢ . validation;	➢ 確效；
➢ . equipment assembly and calibration;	➢ 設備之組裝與校正；

➢ . maintenance, cleaning and sanitization;	➢ 維護保養、清潔與滅菌處理；
➢ personnel matters including training, clothing, hygiene;	➢ 人事事務，包括教育訓練、衣著及衛生；
➢ . environmental monitoring;	➢ 環境監測；
➢ . pest control;	➢ 防鼠防蟲；
➢ . complaints;	➢ 申訴；
➢ . recalls;	➢ 回收；
➢ . returns.	➢ 退回.
4.27. Clear operating procedures should be available for major items of manufacturing and test equipment.	4.27. 主要的製造與檢驗設備應有清楚的作業程序。
4.28. Log books should be kept for major or critical equipment recording, as appropriate, any validations, calibrations, maintenance, cleaning or repair operations, including the dates and identity of people who carried these operations out.	4.28. 適當時，應保存主要或關鍵設備之任何確效、校正、維護保養、清潔或修護作業之記錄的日誌，包括日期及執行這些作業者的身分。
4.29. Log books should also record in chronological order the use of major or critical equipment and the areas where the products have been processed.	4.29. 日誌也應以時序記錄主要或關鍵設備的使用及處理/操作這些產品的區域。

第五章　生產（PRODUCTION）

原則（PRINCIPLE）	
Production operations must follow clearly defined procedures; they must comply with the principles of Good Manufacturing Practice in order to obtain products of the requisite quality and be in accordance with the relevant manufacturing and marketing authorisations.	生產作業應遵循清楚界定的程序，且依從優良製造準則的原則，以獲得要求之品質的產品，並應符合相關的製造和上市的許可。
一般規定（GENERAL）	
5.1. Production should be performed and supervised by competent people.	5.1. 生產應由能勝任者執行與監督。
5.2. All handling of materials and products, such as receipt and quarantine, sampling, storage, labelling, dispensing, processing, packaging and distribution should be done in accordance with written procedures or instructions and, where necessary, recorded.	5.2. 原物料與產品的一切處理，例如接收及待驗、抽樣、儲存、標示、調配、製造、分/包裝及運銷，應依書載程序或指令執行之，必要時並應予記錄。
5.3. All incoming materials should be checked to ensure that the consignment corresponds to the order. Containers should be cleaned where necessary and labelled with the prescribed data.	5.3. 一切進廠的原物料應予核對，以確保託運物與訂單相符。必要時，容器應予清潔，並以規定的資料標示之。
5.4. Damage to containers and any other problem which might adversely affect the quality of a material should be investigated, recorded and reported to the Quality Control Department.	5.4. 容器的破損及對原物料品質可能產生不利影響的任何其他問題，應予調查、記錄，並提報給品質管制部門。
5.5. Incoming materials and finished products should be physically or administratively quarantined immediately after receipt or processing, until they have been released for use or distribution.	5.5. 進廠原物料及最終產品在接收或加工後，應即為實體或行政管理上的隔離，直到它們已經為供使用或運銷而放行為止。
5.6. Intermediate and bulk products purchased as such should be handled on receipt as though they were starting materials.	5.6. 採購的半製品/中間產品或待分/包裝產品，在接收時應把它們視同原料處理。

5.7. All materials and products should be stored under the appropriate conditions established by the manufacturer and in an orderly fashion to permit batch segregation and stock rotation.	5.7. 一切原物料及產品皆應在藥廠建立的適當條件下，並以有條理的方式儲存之，以容許批次的區隔及庫存品的輪換。
5.8. Checks on yields, and reconciliation of quantities, should be carried out as necessary to ensure that there are no discrepancies outside acceptable limits.	5.8. 必要時，應執行產率/產量的核對，以及數量的調和，以確保無超出合格標準範圍的差異。
5.9. Operations on different products should not be carried out simultaneously or consecutively in the same room unless there is no risk of mix-up or cross-contamination.	5.9. 除非無混雜或交叉污染的風險，否則，不同產品的生產作業，不得在同一作業室內同時或接續地執行。
5.10. At every stage of processing, products and materials should be protected from microbial and other contamination.	5.10. 在製程的每一階段，皆應防止產品及原物料受微生物及其他污染。
5.11. When working with dry materials and products, special precautions should be taken to prevent the generation and dissemination of dust. This applies particularly to the handling of highly active or sensitising materials.	5.11. 當處理乾燥的原物料和產品時，應採取特別防範措施，以防止粉塵的產生和散佈。這特別適用於高活性或高致敏性物質的處理。
5.12. At all times during processing, all materials, bulk containers, major items of equipment and where appropriate rooms used should be labelled or otherwise identified with an indication of the product or material being processed, its strength (where applicable) and batch number. Where applicable, this indication should also mention the stage of production.	5.12. 在操作全程中，一切原物料、半製品容器、設備的主要部分及合適時使用的操作室皆應標識，或以加工的產品或原物料、其含量 (如果可行)和批號等標示識別之。可行時，這個標示還應提示其生產的階段。
5.13. Labels applied to containers, equipment or premises should be clear, unambiguous and in the company's agreed format. It is often helpful in addition to the wording on the labels to use colours to indicate status (for example, quarantined, accepted, rejected, clean, ...).	5.13. 用在容器、設備或廠房設施的標籤應清楚、明確，並以公司同意的格式。在標籤上除文字外，使用顏色標示狀況(例如：待驗、合格、拒用、清潔…等)，常是有幫助的。

5.14. Checks should be carried out to ensure that pipelines and other pieces of equipment used for the transportation of products from one area to another are connected in a correct manner.	5.14. 應執行檢查/核對，以確保用以將產品從一個區域輸送到另外一個區域的管路和其他段落的設備是以正確的方式相連接。
5.15. Any deviation from instructions or procedures should be avoided as far as possible. If a deviation occur, it should be approved in writing by a competent person, with the involvement of the Quality Control Department when appropriate.	5.15. 應儘可能避免來自指令或作業程序的任何偏差。發生偏差時，應由權責人員以書面認可，適當時需有品質管制部門的參與。
5.16. Access to production premises should be restricted to authorised personnel.	5.16. 進入生產廠房應限於被授權人員。
5.17. Normally, the production of non-medicinal products should be avoided in areas and with the equipment destined for the production of medicinal products.	5.17. 通常，非藥品之生產應避免在預定生產藥品的區域與設備中為之。
生產中交叉污染的防止 （PREVENTION OF CROSS-CONTAMINATION IN PRODUCTION）	
5.18. Contamination of a starting material or of a product by another material or product must be avoided. This risk of accidental cross-contamination arises from the uncontrolled release of dust, gases, vapours, sprays or organisms from materials and products in process, from residues on equipment, and from operators' clothing. The significance of this risk varies with the type of contaminant and of product being contaminated. Amongst the most hazardous contaminants are highly sensitising materials, biological preparations containing living organisms, certain hormones, cytotoxics, and other highly active materials. Products in which contamination is likely to be most significant are those administered by injection, those given in large doses and/or over a long time.	5.18. 應防止原料或產品為另一原物料或產品所污染。該意外交叉污染的風險，因在製造中之原物料和產品的粉塵、氣體、蒸氣、噴霧或微生物之未加管制的釋放，因設備上的殘留物，以及因作業人員的服裝而引起。該風險的嚴重性隨污染物的種類和被污染的產品而異。其中最具危害的污染物是高致敏性物質、含有生物活體的生物製劑、某些荷爾蒙類、細胞毒類，以及其他高活性的物質。污染對其可能最具重要性的產品是以注射、以大劑量及/或長期投用的那些產品。

5.19. Cross-contamination should be avoided by appropriate technical or organisational measures, for example:	5.19. 交叉污染應以適當的技術或組織的措施避免之，例如:
a) production in segregated areas (required for products such as penicillins, live vaccines, live bacterial preparations and some other biologicals), or by campaign (separation in time) followed by appropriate cleaning;	a) 在隔離的區域(這是對諸如青黴素類、活疫苗、活細菌製劑及一些其他生物性製劑的產品所要求的)，或採分隔時段切換生產，其後應緊接著適當的清潔處理；
b) providing appropriate air-locks and air extraction;	b) 備有適當的氣鎖室及空氣抽除設備；
c) minimising the risk of contamination caused by recirculation or re-entry of untreated or insufficiently treated air;	c) 將未經處理或未經充分處理的空氣之再循環或再進入所引起的污染風險降到最低。
d) keeping protective clothing inside areas where products with special risk of cross-contamination are processed;	d) 在製造具有交叉污染之特別風險之產品的區域內應保持穿著防護裝；
e) using cleaning and decontamination procedures of known effectiveness, as ineffective cleaning of equipment is a common source of cross contamination;	e) 因為設備的無效清潔是交叉污染的一個普遍來源，所以應使用已知之有效的清潔及去污染程序；
f) using "closed systems" of production;	f) 使用密閉的生產系統；
g) testing for residues and use of cleaning status labels on equipment.	g) 測試設備上的殘留物並使用清潔狀態的標籤。
5.20. Measures to prevent cross-contamination and their effectiveness should be checked periodically according to set procedures.	5.20. 5.20. 應依規定的程序定期查核/核對防止交叉污染的措施及其有效性。
確效（Validation ）	
5.21. Validation studies should reinforce Good Manufacturing Practice and be conducted in accordance with defined procedures. Results and conclusions should be recorded.	5.21. 確效研究應強化優良製造準則，並按照所界定的程序實施。其結果和結論應予記錄。
5.22. When any new manufacturing formula or method of preparation is adopted, steps should be taken to demonstrate its suitability for routine processing. The defined process, using the materials and equipment specified, should be shown to yield a product consistently of the required quality.	5.22. 當採用任何新的製造配方或製備方法時，應採取步驟證明其對例行操作的適用性。在使用規定的原物料及設備時，該界定的製程應表現其能生產與要求的品質一致之產品。

5.23. Significant amendments to the manufacturing process, including any change in equipment or materials, which may affect product quality and/or the reproducibility of the process should be validated.	5.23. 對製造過程可能會影響產品品質及/或製程之再現性的重大修正，包括設備或原物料的任何變更，應加以確效。
5.24. Processes and procedures should undergo periodic critical revalidation to ensure that they remain capable of achieving the intended results.	5.24. 製程和程序應經定期的關鍵性再確效，以確保其維持達成預定結果的能力。
原料（STARTING MATERIALS）	
5.25. The purchase of starting materials is an important operation which should involve staff who have a particular and thorough knowledge of the suppliers.	5.25. 原料的採購是一項重要的作業，應有對供應商具有特別且充分瞭解的人員參與。
5.26. Starting materials should only be purchased from approved suppliers named in the relevant specification and, where possible, directly from the producer. It is recommended that the specifications established by the manufacturer for the starting materials be discussed with the suppliers. It is of benefit that all aspects of the production and control of the starting material in question, including handling, labelling and packaging requirements, as well as complaints and rejection procedures are discussed with the manufacturer and the supplier.	5.26. 原料只可向在相關規格上列名之經認可的供應商購買；可能時，應直接向生產者購買。建議藥廠要就建立之原料規格與供應商討論。所涉原料之生產與管制的一切層面，包括其處理、標示、分/包裝的要求，以及申訴和拒用的程序等，與製造廠和供應商討論是有助益的。
5.27. For each delivery, the containers should be checked for integrity of package and seal and for correspondence between the delivery note and the supplier's labels.	5.27. 每一次交貨，應檢查/核對容器的包裝和封條的完整性及送貨單與供應商的標示間之一致性。
5.28. If one material delivery is made up of different batches, each batch must be considered as separate for sampling, testing and release.	5.28. 原物料之一次的交貨是由不同的批次所組成者，則為其抽樣、測試與放行，每一批次應各自考慮。

5.29. Starting materials in the storage area should be appropriately labelled (see Chapter 5, Item 13). Labels should bear at least the following information:	5.29. 在儲存區的原料應適當地標示 (請參見第五章，第十三項)。標籤上應至少記載下列資料：
➢ the designated name of the product and the internal code reference where applicable;	➢ 產品的指定名稱及其內部參考代碼(可行時)；
➢ a batch number given at receipt;	➢ 在接收時所給予的批號；
➢ where appropriate, the status of the contents (e.g. in quarantine, on test, released, rejected);	➢ 合適時，內容物的狀態(例如：待驗中、檢驗中、放行、拒用)；
➢ where appropriate, an expiry date or a date beyond which retesting is necessary.	➢ 合適時，末效日期或過了該日便應再測試的日期。
When fully computerised storage systems are used, all the above information should not necessarily be in a legible form on the label.	採用完全電腦化之儲存系統者，上述全部資料不必以易讀的方式印在標籤上。
5.30. There should be appropriate procedures or measures to assure the identity of the contents of each container of starting material. Bulk containers from which samples have been drawn should be identified (see Chapter 6, Item 13).	5.30. 應有適當的程序或措施來確保每個原料容器之內容物的同一性。已經抽取樣品之大包裝容器的同一性應予辨識。
5.31. Only starting materials which have been released by the Quality Control Department and which are within their shelf-life should be used.	5.31. 只有經品質管制部門放行且還在其架儲期間內的原料始可使用。
5.32. Starting materials should only be dispensed by designated persons, following a written procedure, to ensure that the correct materials are accurately weighed or measured into clean and properly labelled containers.	5.32. 原料只得由指定的人員依書載程序調配，以確保正確的原物料經準確地秤入或量入潔淨且適切標示的容器中。
5.33. Each dispensed material and its weight or volume should be independently checked and the check recorded.	5.33. 每一調配過的原物料及其重量或容量，皆應獨立檢查，並將該檢查記錄之。
5.34. Materials dispensed for each batch should be kept together and conspicuously labelled as such.	5.34. 為每一批次調配的原物料應保存在一起，並顯著地標示。

半製品/中間產品和待分/包裝產品的操作作業 （PROCESSING OPERATIONS INTERMEDIATE AND BULK PRODUCTS）	
5.35. Before any processing operation is started, steps should be taken to ensure that the work area and equipment are clean and free from any starting materials, products, product residues or documents not required for the current operation.	5.35. 在任何操作作業開始前，應採取步驟，以確保作業區和設備是潔淨且無任何現行作業所不需要的原料、產品、產品殘留物或文件。
5.36. Intermediate and bulk products should be kept under appropriate conditions.	5.36. 半製品/中間產品或待分/包裝產品應保存在適當的條件下。
5.37. Critical processes should be validated (see "VALIDATION" in this Chapter).	5.37. 關鍵製程應經確效(請參見本章之“確效”節段)。
5.38. Any necessary in-process controls and environmental controls should be carried out and recorded.	5.38. 任何必要的製程中管制和環境管制均應執行並予記錄。
5.39. Any significant deviation from the expected yield should be recorded and investigated.	5.39. 與預期產率/產量的任何顯著偏差均應予記錄並加以調查。
包裝材料（PACKAGING MATERIALS）	
5.40. The purchase, handling and control of primary and printed packaging materials should be accorded attention similar to that given to starting materials.	5.40. 就直接的及印刷的包裝材料之採購、處理和管制應類似於原料給予同一之注意。
5.41. Particular attention should be paid to printed materials. They should be stored in adequately secure conditions such as to exclude unauthorised access. Cut labels and other loose printed materials should be stored and transported in separate closed containers so as to avoid mix-ups. Packaging materials should be issued for use only by authorised personnel following an approved and documented procedure.	5.41. 對印刷的包裝材料應給予特別注意。該材料應儲存在足夠安全的條件中，使其足以排除未經授權的取用。切式標籤和其他散裝之印好的包裝材料應在分別的密閉容器中儲存與搬運，以免混雜。包裝材料應只得由被授權的人員，依認可的並經文件化的程序發放使用。
5.42. Each delivery or batch of printed or primary packaging material should be given a specific reference number or identification mark.	5.42. 每次交貨或每一批次之印刷的或直接的包裝材料，均應給予一個專有的參考號碼或辨識標記。

5.43. Outdated or obsolete primary packaging material or printed packaging material should be destroyed and this disposal recorded.	5.43. 過期的或作廢的直接的包裝材料或印刷的包裝材料應予銷毀，並將該處置加以記錄。
分/包裝作業（PACKAGING OPERATIONS）	
5.44. When setting up a programme for the packaging operations, particular attention should be given to minimising the risk of cross-contamination, mix-ups or substitutions. Different products should not be packaged in close proximity unless there is physical segregation.	5.44. 在建立分/包裝作業計畫時應特別注意，以將交叉污染、混雜、或替代的風險降到最低。除非有實體的分隔，不同的產品不得在緊密相鄰處分/包裝。
5.45. Before packaging operations are begun, steps should be taken to ensure that the work area, packaging lines, printing machines and other equipment are clean and free from any products, materials or documents previously used, if these are not required for the current operation. The line-clearance should be performed according to an appropriate check-list.	5.45. 在分/包裝作業開始前應採取步驟，以確保作業區、分/包裝線、印刷機及其他設備是潔淨的，且無現行作業所不要求之先前使用的任何產品、原物料或文件。分/包裝線的清線應依適當的查檢表執行之。
5.46. The name and batch number of the product being handled should be displayed at each packaging station or line.	5.46. 處理中的產品名稱及批號，應標明在每個分/包裝站或線上。
5.47. All products and packaging materials to be used should be checked on delivery to the packaging department for quantity, identity and conformity with the Packaging Instructions.	5.47. 將要使用的一切產品及包裝材料，在交給分/包裝部門時皆應檢查/核對其數量、代號/名稱並與分/包裝指令相符。
5.48. Containers for filling should be clean before filling. Attention should be given to avoiding and removing any contaminants such as glass fragments and metal particles.	5.48. 充填用的容器在充填前應是潔淨的。應注意避免並移除任何污染物，例如玻璃碎片及金屬粒子。
5.49. Normally, filling and sealing should be followed as quickly as possible by labelling. If it is not the case, appropriate procedures should be applied to ensure that no mix-ups or mislabelling can occur.	5.49. 通常，在充填與密封之後應儘快加以標示。若非如是，則應採取適當的程序，以確保不會發生混雜或貼錯標籤。

5.50. The correct performance of any printing operation (for example code numbers, expiry dates) to be done separately or in the course of the packaging should be checked and recorded. Attention should be paid to printing by hand which should be re-checked at regular intervals.	5.50. 應分別或要在分/包裝過程中從事之任何印刷作業（例如代碼、末效日期）的正確執行應予檢查/核對並加以記錄。手工印刷應予注意，並應定時再予檢查/核對。
5.51. Special care should be taken when using cut-labels and when over-printing is carried out off-line. Roll-feed labels are normally preferable to cut-labels, in helping to avoid mix-ups.	5.51. 當使用切式標籤和執行離線套印時，應予特別注意。在幫助避免混雜上，轉筒式標籤通常優於切式標籤。
5.52. Checks should be made to ensure that any electronic code readers, label counters or similar devices are operating correctly.	5.52. 為確保電子讀碼機、標籤計數器或其他類似的裝置是在正確操作，應執行查核/核對。
5.53. Printed and embossed information on packaging materials should be distinct and resistant to fading or erasing.	5.53. 印刷或凸印在包裝材料上的資訊，應明顯且能阻抗褪色或擦除。
5.54. On-line control of the product during packaging should include at least checking the following:	5.54. 在分/包裝期間，產品的線上管制應包括至少檢查/核對下列事項：
a) general appearance of the packages;	a) 包裝的一般外觀；
b) whether the packages are complete;	b) 包裝是否完整；
c) whether the correct products and packaging materials are used;	c) 是否使用正確的產品與包裝材料;
d) whether any over-printing is correct;	d) 任何套印是否正確；
e) correct functioning of line monitors.	e) 分/包裝線上監視器的正確運轉。
Samples taken away from the packaging line should not be returned.	從分/包裝線上取出的樣品不得置回。
5.55. Products which have been involved in an unusual event should only be reintroduced into the process after special inspection, investigation and approval by authorised personnel. Detailed record should be kept of this operation.	5.55. 已經涉及異常事件的產品，須經被授權人員的特別查核、調查及認可後，始得再導入分/包裝過程中。應保存該作業之詳細紀錄。
5.56. Any significant or unusual discrepancy observed during reconciliation of the amount of bulk product and printed	5.56. 在待分/包裝產品與印刷之包裝材料的數量，和產出單元數目間的數量調和中，觀察到之任何顯著或異常的差異應予調

packaging materials and the number of units produced should be investigated and satisfactorily accounted for before release.	查，並在放行前滿意地說明之。
5.57. Upon completion of a packaging operation, any unused batch-coded packaging materials should be destroyed and the destruction recorded. A documented procedure should be followed if uncoded printed materials are returned to stock.	5.57. 分/包裝作業完成後，任何未使用而印有批號的印刷包裝材料應予銷毀，並將該銷毀加以記錄。有未印批號之材料要退回庫存者，應遵循書載程序。
最終產品（FINISHED PRODUCTS）	
5.58. Finished products should be held in quarantine until their final release under conditions established by the manufacturer.	5.58. 最終產品在其依藥廠制訂之條件最終放行前，應保持於隔離/待驗區。
5.59. The evaluation of finished products and documentation which is necessary before release of product for sale are described in Chapter 6 (Quality Control).	5.59. 在產品為供販售放行前，最終產品與文件所需之評估規定於第六章(品質管制)。
5.60. After release, finished products should be stored as usable stock under conditions established by the manufacturer.	5.60. 最終產品在放行後應依藥廠制訂的條件當成可用的庫存品儲存。
拒用的、收回的以及退回的原物料（REJECTED, RECOVERED AND RETURNED MATERIALS）	
5.61. Rejected materials and products should be clearly marked as such and stored separately in restricted areas. They should either be returned to the suppliers or, where appropriate, reprocessed or destroyed. Whatever action is taken should be approved and recorded by authorised personnel.	5.61. 拒用的原物料和產品應清楚標識其係拒用物品，並分別儲存於限制區中。該物品應退回供應商，或於合適時，予以再製或銷毀。不論採取任何行動皆應經被授權人員的認可並予記錄。
5.62. The reprocessing of rejected products should be exceptional. It is only permitted if the quality of the final product is not affected, if the specifications are met and if it is done in accordance with a defined and authorised procedure after evaluation of the risks involved. Record should be kept of the reprocessing.	5.62. 拒用產品的重製/重處理應屬例外。只有在最終產品的品質不受影響、符合規格，且經評估所涉風險後，依界定且經認可的程序執行時，方始允許。重製/重處理的紀錄應予保存。

5.63. The recovery of all or part of earlier batches, which conform to the required quality by incorporation into a batch of the same product at a defined stage of manufacture should be authorised beforehand. This recovery should be carried out in accordance with a defined procedure after evaluation of the risks involved, including any possible effect on shelf life. The recovery should be recorded.	5.63. 符合所需品質之先前批次的全部或一部分，在一個界定的製造階段，併入一相同產品之一個批次的收回，應經事先許可。這種收回應在其所涉風險，包含其對架儲期間之任何可能影響之評估後，依一個界定的程序執行之。該收回應予記錄。
5.64. The need for additional testing of any finished product which has been reprocessed, or into which a recovered product has been incorporated, should be considered by the Quality Control Department.	5.64. 就經過重製/重處理或併入收回之產品的任何最終產品，應由品質管制部門考慮其追加測試的必要性。
5.65. Products returned from the market and which have left the control of the manufacturer should be destroyed unless without doubt their quality is satisfactory; they may be considered for re-sale, re-labelling or recovery with a subsequent batch only after they have been critically assessed by the Quality Control Department in accordance with a written procedure. The nature of the product, any special storage conditions it requires, its condition and history, and the time elapsed since it was issued should all be taken into account in this assessment. Where any doubt arises over the quality of the product, it should not be considered suitable for re-issue or re-use, although basic chemical reprocessing to recover active ingredients may be possible. Any action taken should be appropriately recorded.	5.65. 從市場退回以及已經離開藥廠之管制的產品，應予銷毀，除非其品質毫無疑問是令人滿意的；只有在其已經為品質管制部門依書載程序嚴格評估後，才可以考慮重新銷售、重新標示或是併入下一批收回。在這種評估中，產品的性質、它要求的任何特別儲存條件、其狀況與歷史，以及自推出後已經經過的時間等均應列入考慮。縱使基本的化學再處理能使有效成分收回，只要對此產品的品質產生任何疑問，就不得認為其還適合重新出貨或重新使用。採取的任何行動皆應予適當地記錄。

第六章　品質管制（QUALITY CONTROL）

原則（PRINCIPLE）	
Quality Control is concerned with sampling, specifications and testing as well as the organisation, documentation and release procedures which ensure that the necessary and relevant tests are carried out, and that materials are not released for use, nor products released for sale or supply, until their quality has been judged satisfactory. Quality Control is not confined to laboratory operations, but must be involved in all decisions which may concern the quality of the product. The independence of Quality Control from Production is considered fundamental to the satisfactory operation of Quality Control (see also Chapter 1).	品質管制與抽樣、規格與試驗以及組織、文件與放行程序有關。這用以確保必要的與相關的試驗皆已執行，也確保在品質經判斷滿意前，無原物料會被放行以供使用，無產品會被放行以供銷售或供應。品質管制不侷限於實驗室的作業，而應涉及可能與該產品品質有關的一切決定。將品質管制部門從生產部門獨立出來被認為是品質管制之滿意運作的基礎。
一般規定（GENERAL）	
6.1. Each holder of a manufacturing authorisation should have a Quality Control Department. This department should be independent from other departments, and under the authority of a person with appropriate qualifications and experience, who has one or several control laboratories at his disposal. Adequate resources must be available to ensure that all the Quality Control arrangements are effectively and reliably carried out.	6.1. 每一個製造許可的持有者均應有一個品質管制部門。該部門應從其他部門獨立出來，並由一位具有適當資格和經驗的人負責。他/她擁有由其支配的一個或多個管制實驗室。該部門應有適當的資源，以確保有效地且可靠地執行一切品質管制的安排。
6.2. The principal duties of the head of Quality Control are summarised in Chapter 2. The Quality Control Department as a whole will also have other duties, such as to establish, validate and implement all quality control procedures, keep the reference samples of materials and products, ensure the correct labelling of containers of materials and products, ensure the monitoring of the stability of	6.2. 品質管制主管的主要職責概述於第二章。整體而言，品質管制部門也有其他的職責，例如：要制訂、確效、並執行一切品質管制程序，保存原物料與產品的對照樣品，確保原物料與產品容器的正確標示，確保產品安定性的監測，參與和產品品質有關之申訴的調查等。這些作業均應依書載程序執行，且在必要時，應予記錄。

the products, participate in the investigation of complaints related to the quality of the product, etc. All these operations should be carried out in accordance with written procedures and, where necessary, recorded.	
6.3. Finished product assessment should embrace all relevant factors, including production conditions, results of in-process testing, a review of manufacturing (including packaging) documentation, compliance with Finished Product Specification and examination of the final finished pack.	6.3. 最終產品的評價應包含一切相關的因素，包括生產條件、製程中測試的結果、製造(包括分/包裝)文件的檢討、符合最終產品規格以及最終包裝產品的檢查。
6.4. Quality Control personnel should have access to production areas for sampling and investigation as appropriate.	6.4. 為抽樣與調查，合適時，品質管制人員應進入生產區。
優良品質管制實驗室規範 （GOOD QUALITY CONTROL LABORATORY PRACTICE）	
6.5. Control Laboratory premises and equipment should meet the general and specific requirements for Quality Control areas given in Chapter 3.	6.5. 管制實驗室的廠房及設備應符合第三章所定品質管制區之一般和特別的要求。
6.6. The personnel, premises, and equipment in the laboratories should be appropriate to the tasks imposed by the nature and the scale of the manufacturing operations. The use of outside laboratories, in conformity with the principles detailed in Chapter 7, Contract Analysis, can be accepted for particular reasons, but this should be stated in the Quality Control records.	6.6. 實驗室中的人員、廠房及設備應與該製造作業的性質與規模所須執行的工作相稱。在符合第 7 章委/受託檢驗所詳述的原則下，有特別的理由者，得接受使用外部實驗室。這應在品質管制紀錄中加以陳述。
文件（DOCUMENTATION）	
6.7. Laboratory documentation should follow the principles given in Chapter 4. An important part of this documentation deals with Quality Control and the following details should be readily available to the Quality Control Department:	6.7. 實驗室文件的製作應遵照第四章所定的原則。與品質管制有關的重要文件以及下列細節資料應備供品質管制部門取用：

➢ specifications;	➢ 規格；
➢ sampling procedures;	➢ 抽樣程序；
➢ testing procedures and records (including analytical worksheets and/or laboratory notebooks);	➢ 測試程序和紀錄(包括分析工作單及/或實驗室的筆記本)；
➢ analytical reports and/or certificates;	➢ 分析報告及/或檢驗證明書；
➢ data from environmental monitoring, where required;	➢ 環境監測資料（要求時）；
➢ validation records of test methods, where applicable;	➢ 試驗方法的確效紀錄（可行時）；
➢ procedures for and records of the calibration of instruments and maintenance of equipment.	➢ 儀器校正與設備維護保養的程序及紀錄。
6.8. Any Quality Control documentation relating to a batch record should be retained for one year after the expiry date of the batch.	6.8. 與一批次紀錄有關的任何品質管制文件，應保存至該批次產品的末效日期後一年。
6.9. For some kinds of data (e.g. analytical tests results, yields, environmental controls, ...) it is recommended that records in a manner permitting trend evaluation be kept.	6.9. 某些類型的數據 (如：分析試驗結果、產率/產量、環境的管制…等)建議應以容許趨勢評估的方式保存其紀錄。
6.10. In addition to the information which is part of the batch record, other original data such as laboratory notebooks and/or records should be retained and readily available.	6.10. 除批次紀錄之一部分的資訊外，其他原始資料，例如實驗室筆記本及/或紀錄，皆應予保存並且易於取用。
抽樣（SAMPLING）	
6.11. The sample taking should be done in accordance with approved written procedures that describe:	6.11. 抽樣應依經認可之書載程序執行。該程序描述：
➢ the method of sampling;	➢ 抽樣的方法；
➢ the equipment to be used;	➢ 要使用的設備；
➢ the amount of the sample to be taken;	➢ 要抽取的樣品數量；
➢ instructions for any required sub-division of the sample;	➢ 任何要求將樣品再細分的指令；
➢ the type and condition of the sample container to be used;	➢ 要使用之樣品容器的型式及條件；

➢ the identification of containers sampled;	➢ 抽取樣品之容器的辨識；
➢ any special precautions to be observed, especially with regard to the sampling of sterile or noxious materials;	➢ 應遵行的任何特別注意事項，特別是關於無菌的或是有毒物質的抽樣；
➢ the storage conditions;	➢ 儲存條件；
➢ instructions for the cleaning and storage of sampling equipment.	➢ 抽樣設備之清潔與儲存的指令。
6.12. Reference samples should be representative of the batch of materials or products from which they are taken. Other samples may also be taken to monitor the most stressed part of a process (e.g. beginning or end of a process).	6.12. 對照樣品對於其取自之原物料或產品批次應有代表性。也可另取其他樣品，用以監測一個製程之最困難的部分(例如：一個製程的開始和結束)。
6.13. Sample containers should bear a label indicating the contents, with the batch number, the date of sampling and the containers from which samples have been drawn.	6.13. 樣品容器的標籤應標識其內容物、批號、抽樣日期以及樣品所取自之容器。
6.14. Reference samples from each batch of finished products should be retained till one year after the expiry date. Finished products should usually be kept in their final packaging and stored under the recommended conditions. Samples of starting materials (other than solvents, gases and water) should be retained for at least two years after the release of the product if their stability allows. This period may be shortened if their stability, as mentioned in the relevant specification, is shorter. Reference samples of materials and products should be of a size sufficient to permit at least a full re-examination.	6.14. 來自每批最終產品的對照樣品應儲存至該批產品之末效日期後一年。最終產品通常應保存在其最終包裝中，並儲存在建議的條件下。原料之安定性容許者，原料(不包括溶劑、氣體及水)的樣品應保存至該產品放行後至少兩年。在相關規格中提到其安定性較短者，該兩年的保存期限得縮短之。原物料及產品之參考樣品的數量應足供至少再執行一次完整的再檢查。[1]
測試（TESTING）	
6.15. Analytical methods should be validated. All testing operations described in the marketing authorisation should be carried out according to the approved methods.	6.15. 分析方法應予確效。在上市許可中所描述的一切測試作業皆應依經認可的方法執行之。
6.16. The results obtained should be recorded and checked to make sure that they are	6.16. 獲得的結果應予記錄並檢查/核對，以確

consistent with each other. Any calculations should be critically examined.	保彼此間是一致的。任何計算均應予嚴格驗算。
6.17. The tests performed should be recorded and the records should include at least the following data:	6.17. 執行的試驗應予記錄，且這些紀錄至少應包括下列資料:
a) name of the material or product and, where applicable, dosage form;	a) 原物料或產品名稱，及其劑型(可行時)；
b) batch number and, where appropriate, the manufacturer and/or supplier;	b) 批號，及其製造廠及/或供應商(合適時)；
c) references to the relevant specifications and testing procedures;	c) 相關規格與試驗程序的參考資料；
d) test results, including observations and calculations, and reference to any certificates of analysis;	d) 測試的結果，包括觀測、計算和任何檢驗證明書的參考資料；
e) dates of testing;	e) 測試日期；
f) initials of the persons who performed the testing;	f) 執行該測試之人員的簽名；
g) initials of the persons who verified the testing and the calculations, where appropriate;	g) 合適時，驗證該測試及該計算之人員的簽名；
h) a clear statement of release or rejection (or other status decision) and the dated signature of the designated responsible person.	h) 放行或拒用(或其他狀態的決定)之清楚說明及指定之負責人註明日期的簽章。
6.18. All the in-process controls, including those made in the production area by production personnel, should be performed according to methods approved by Quality Control and the results recorded.	6.18. 一切製程中管制，包括由生產人員在生產區中所執行的那些管制，應依品質管制部門認可的方法執行，並記錄其結果。
6.19. Special attention should be given to the quality of laboratory reagents, volumetric glassware and solutions, reference standards and culture media. They should be prepared in accordance with written procedures.	6.19. 應特別注意實驗室試劑、容量玻璃器皿及溶液、對照標準品以及培養基的品質。它們應依書載的程序製備之。
6.20. Laboratory reagents intended for prolonged use should be marked with the preparation date and the signature of the person who prepared them. The expiry date of unstable reagents and culture	6.20. 預定供長期使用的實驗室試劑，應標記其配製日期及配製人員的簽章。不穩定的試劑及培養基的末效日期，應與其特別的儲存條件一同標示在標籤上。此

media should be indicated on the label, together with specific storage conditions. In addition, for volumetric solutions, the last date of standardisation and the last current factor should be indicated.	外，對於容量分析溶液，應標示其最近一次標定日期及最近的換算係數。
6.21. Where necessary, the date of receipt of any substance used for testing operations (e.g. reagents and reference standards) should be indicated on the container. Instructions for use and storage should be followed. In certain cases it may be necessary to carry out an identification test and/or other testing of reagent materials upon receipt or before use.	6.21. 必要時，應將用於測試作業之任何物質(例如：試劑及對照標準品)的接收日期標識在容器上。使用及儲存的指令應予遵循。在某些情形，於接收時或使用前，可能有必要執行試劑材料的鑑別試驗及/或其他試驗。
6.22. Animals used for testing components, materials or products, should, where appropriate, be quarantined before use. They should be maintained and controlled in a manner that assures their suitability for the intended use. They should be identified, and adequate records should be maintained, showing the history of their use.	6.22. 用於測試組成物/組件、原物料或產品的動物，合適時，使用前應予隔離。它們應以能確保其合於預定用途之適用性的方式飼養維護及管制。它們應予辨識，並保存顯示其使用歷程之適當紀錄。
持續進行之安定性計畫（ON-GOING STABILITY PROGRAMME）	
6.23. After marketing, the stability of the medicinal product should be monitored according to a continuous appropriate programme that will permit the detection of any stability issue (e.g. changes in levels of impurities, or dissolution profile) associated with the formulation in the marketed package.	6.23. 藥品上市後，其安定性應依照一個持續的適當計畫進行監測。該計畫將容許檢出與上市包裝中的配方組成關聯之任何安定性的問題【例如，在雜質/不純物含量，或溶離圖像描述的變化】。
6.24. The purpose of the on-going stability programme is to monitor the product over its shelf life and to determine that the product remains, and can be expected to remain, within specifications under the labelled storage conditions.	6.24. 持續進行的安定性計畫之目的是要在產品架儲期全期中監測該產品，並確定在所標示的儲存條件下，該產品保持，而且可以預期保持在規格內。
6.25. This mainly applies to the medicinal product in the package in which it is sold,	6.25. 這主要應用於包裝藥品之販售，但也應考慮將待分/包裝產品包括到計畫中來。

but consideration should also be given to the inclusion in the programme of bulk product. For example, when the bulk product is stored for a long period before being packaged and/or shipped from a manufacturing site to a packaging site, the impact on the stability of the packaged product should be evaluated and studied under ambient conditions. In addition, consideration should be given to intermediates that are stored and used over prolonged periods. Stability studies on reconstituted product are performed during product development and need not be monitored on an on-going basis. However, when relevant, the stability of reconstituted product can also be monitored.	例如，當待分/包裝產品在包裝前，及/或從一個製造場所裝運到一個包裝場所前，儲存一段長的期間時，其對於包裝產品之安定性的衝擊應加以評估，並在常溫條件下（週遭條件下）研究之。此外，對於歷經長期間之儲存與使用的中間產品也應給予考慮。臨用調配之產品的安定性之研究已在產品開發期間執行者，不需要在一個持續進行的基礎上監測之。不過，臨用調配之產品的安定性於合適時也可以加以監測。
6.26. The on-going stability programme should be described in a written protocol following the general rules of Chapter 4 and results formalised as a report. The equipment used for the on-going stability programme (stability chambers among others) should be qualified and maintained following the general rules of Chapter 3 and annex 15.	6.26. 持續進行之安定性計畫，應遵循第 4 章的一般規則，以書面計畫書描述之，並將其結果正式作成一個報告。使用於持續進行之安定性計畫的設備 (尤其是安定性艙室)應依循第 3 章與第 15 分則加以驗證並予維護。
6.27. The protocol for an on-going stability programme should extend to the end of the shelf life period and should include, but not be limited to, the following parameters:	6.27. 對於一個持續進行之安定性計畫的計畫書，應涵蓋至架儲期間的終點，並且應包括，但不限於下列的參數：
• number of batch(es) per strength and different batch sizes, if applicable	• 每一種含量與（合適時）不同批量之批次的數目
• relevant physical, chemical, microbiological and biological test methods	• 相關的物理、化學、微生物學以及生物學的試驗方法
• acceptance criteria	• 允收基準
• reference to test methods	• 試驗方法的參考資料
• description of the container closure system(s)	• 容器封蓋系統的描述

• testing intervals (time points)	• 測試間隔（時間點）
• description of the conditions of storage (standardised ICH conditions for long term testing, consistent with the product labelling, should be used)	• 儲存條件的描述(應使用 ICH 對於長期測試之與產品標示一致的標準化條件)
• other applicable parameters specific to the medicinal product.	•其他特別適用於該藥品的參數
6.28. The protocol for the on-going stability programme can be different from that of the initial long-term stability study as submitted in the marketing authorisation dossier provided that this is justified and documented in the protocol (for example the frequency of testing, or when updating to ICH recommendations).	6.28. 在計畫書中證明其正當性並予文件化者，其持續進行之安定性計畫的計畫書得與當初在上市許可檔案中所提交之長期安定性研究的計畫書不同(例如，測試頻率或當對 ICH 建議更新時)。
6.29. The number of batches and frequency of testing should provide a sufficient amount of data to allow for trend analysis. Unless otherwise justified, at least one batch per year of product manufactured in every strength and every primary packaging type, if relevant, should be included in the stability programme (unless none are produced during that year). For products where on-going stability monitoring would normally require testing using animals and no appropriate alternative, validated techniques are available, the frequency of testing may take account of a risk-benefit approach. The principle of bracketing and matrixing designs may be applied if scientifically justified in the protocol.	6.29. 批次數目與測試頻率應能提供足夠的資訊/數據量，以容許趨勢分析。除非另有正當理由，否則，所製造之每一含量?及每一直接包裝類型的產品，相關時，每年至少應有一個批次包含在安定性計畫中(除非該年中沒有生產)。產品之持續進行的安定性監測通常需要使用動物來測試而無適當經確效的替代技術時，其測試頻率可以考慮風險-效益方法（risk-benefit approach）。經在計畫書中科學地證明其正當者，得採用籃狀設計與矩陣設計的原理。
6.30. In certain situations, additional batches should be included in the on-going stability programme. For example, an on-going stability study should be conducted after any significant change or significant deviation to the process or package. Any reworking, reprocessing or recovery operation should also be considered for inclusion.	6.30. 在某些情況中，應在持續進行的安定性計畫中納入追加的批次。例如，在製程或包裝有任何重大改變或重大偏離/偏差後，應從事一個持續進行的安定性研究。任何再加工、重處理/重製或收回作業，也應考慮納入。
6.31. Results of on-going stability studies should be made available to key personnel	6.31. 持續進行之安定性研究的結果，應使關鍵人員，特別是使被授權人員能夠取

and, in particular, to the Authorised Person(s). Where on-going stability studies are carried out at a site other than the site of manufacture of the bulk or finished product, there should be a written agreement between the parties concerned. Results of on-going stability studies should be available at the site of manufacture for review by the competent authority.	得。持續進行的安定性研究係在待分/包裝或最終產品的製造場所以外之另一個場所執行者，相關各方間應有一個書面協議。在製造場所應可取得持續安定性研究的結果，以備供主管機關檢查。
6.32. Out of specification or significant atypical trends should be investigated. Any confirmed out of specification result, or significant negative trend, should be reported to the relevant competent authorities. The possible impact on batches on the market should be considered in accordance with chapter 8 of the GMP Guide and in consultation with the relevant competent authorities.	6.32. 有偏離規格或有重大非典型趨勢時，應予調查。有任何經證實之偏離規格的結果或顯著的負面趨勢時，應向該管主管機關報告。這對於已在市場之批次的可能衝擊應依照優良製造準則指引（GMP Guide）第 8 章，及與該管主管機關之研商結果，加以考慮。
6.33. A summary of all the data generated, including any interim conclusions on the programme, should be written and maintained. This summary should be subjected to periodic review.	6.33. 產生之一切資料/數據的摘要，包含計畫中之任何期中/暫時的結論在內，均應做成書面，並予保存。該摘要應接受定期的檢討。

第七章　委/受託製造與委/受託檢驗
（CONTRACT MANUFACTURE AND ANALYSIS）

原則（PRINCIPLE）	
Contract manufacture and analysis must be correctly defined, agreed and controlled in order to avoid misunderstandings which could result in a product or work of unsatisfactory quality. There must be a written contract between the Contract Giver and the Contract Acceptor which clearly establishes the duties of each party. The contract must clearly state the way in which the authorised person releasing each batch of product for sale exercises his full responsibility.	委/受託製造與委/受託檢驗應正確地予以界定、協議及管制，以避免因誤解而可能導致不滿意之品質的產品或作業。委託者與受託者間應有清楚訂定雙方職責的書面契約。該契約應清楚約定，負責放行每批供銷售之產品的被授權人執行其完整職責的方式。
Note: This Chapter deals with the responsibilities of manufacturers towards the Component Authorities of the Participating authorities with respect to the granting of marketing and manufacturing authorisations. It is not intended in any way to affect the respective liability of contract acceptors and contract givers to consumers.	*註：本章規定對於授予銷售與製造許可之會員主管機關的組成主管機關藥廠應負責任。本章無意以任何方式影響委託者與受託者對於消費者之個別義務。*
一般規定（GENERAL）	
7.1. There should be a written contract covering the manufacture and/or analysis arranged under contract and any technical arrangements made in connection with it.	7.1. 在該委託契約下，應有涵蓋製造及/或委/受託檢驗之書面契約及與之有關的技術安排。
7.2. All arrangements for contract manufacture and analysis including any proposed changes in technical or other arrangements should be in accordance with the marketing authorisation for the product concerned.	7.2. 為委/受託製造與委/受託檢驗之一切安排，包括技術或其他安排中所建議之任何改變，均應符合相關產品之上市許可。

委託者（THE CONTRACT GIVER）	
7.3. The Contract Giver is responsible for assessing the competence of the Contract Acceptor to carry out successfully the work required and for ensuring by means of the contract that the principles and Guidelines of GMP as interpreted in this Guide are followed.	7.3. 委託者應負責評估受託者成功履行要求之工作的能力，並負責藉由該契約，確保本指引所闡釋之優良製造準則(GMP)的原則與指引受到遵循。
7.4. The Contract Giver should provide the Contract Acceptor with all the information necessary to carry out the contracted operations correctly in accordance with the marketing authorisation and any other legal requirements. The Contract Giver should ensure that the Contract Acceptor is fully aware of any problems associated with the product or the work which might pose a hazard to his premises, equipment, personnel, other materials or other products.	7.4. 委託者應提供受託者一切必需的資訊，以使其依上市許可和任何其他法律要求，正確地履行約定的作業。委託者應確保受託者完全認識與本產品或工作有關之任何可能會對其廠房、設備、人員、其他原物料或其他產品造成危害的問題。
7.5. The Contract Giver should ensure that all processed products and materials delivered to him by the Contract Acceptor comply with their specifications or that the products have been released by an authorised person.	7.5. 委託者應確保受託者所交付之一切處理過的產品和原物料均依從其規格，或這些產品係經由被授權人放行。
受託者（THE CONTRACT ACCEPTOR）	
7.6. The Contract Acceptor must have adequate premises and equipment, knowledge and experience, and competent personnel to carry out satisfactorily the work ordered by the Contract Giver. Contract manufacture may be undertaken only by a manufacturer who is the holder of a manufacturing authorisation.	7.6. 受託者應有適當的廠房和設備、知識和經驗、以及能勝任的人員，來滿意地執行委託者所託付的工作。接受委託製造僅得由取得製造許可者為之。
7.7. The Contract Acceptor should ensure that all products or materials delivered to him are suitable for their intended purpose.	7.7. 受託者應確認交付給他/她的一切產品或原物料皆符合其預定之目的。

7.8. 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. Arrangements made between the Contract Acceptor and any third party should ensure that the manufacturing and analytical information is made available in the same way as between the original Contract Giver and Contract Acceptor.	7.8. 受託者未經委託者之事先評估和同意，不得將契約所委託的任何工作轉託給第三人。受託者與任何第三人間所做的任何安排，應確保其製造和檢驗資訊以原委託者與受託者間約定的相同方式提供之。
7.9. The Contract Acceptor should refrain from any activity which may adversely affect the quality of the product manufactured and/or analysed for the Contract Giver.	7.9. 受託者應避免可能不良影響其為委託者製造及/或檢驗之產品品質的任何活動。
合約（THE CONTRACT）	
7.10. A contract should be drawn up between the Contract Giver and the Contract Acceptor which specifies their respective responsibilities relating to the manufacture and control of the product. Technical aspects of the contract should be drawn up by competent persons suitably knowledgeable in pharmaceutical technology, analysis and Good Manufacturing Practice. All arrangements for manufacture and analysis must be in accordance with the marketing authorisation and agreed by both parties	7.10. 委託者與受託者間應締結契約。該契約明定雙方關於產品製造與管制的個別責任。契約中的技術層面應由具有製藥技術、檢驗及優良製造準則之適當知識的勝任人員擬定。製造及檢驗的一切安排均應依上市許可的規定，並為雙方所同意。
7.11. The contract should specify the way in which the authorised person releasing the batch for sale ensures that each batch has been manufactured and checked for compliance with the requirements of Marketing Authorisation.	7.11. 契約應明定被授權人放行供銷售之批次的方式，以確保每一批次皆已依從上市許可的要求而製造與檢查。

7.12. The contract should describe clearly who is responsible for purchasing materials, testing and releasing materials, undertaking production and quality controls, including in-process controls, and who has responsibility for sampling and analysis. In the case of contract analysis, the contract should state whether or not the Contract Acceptor should take samples at the premises of the manufacturer.	7.12. 契約中應清楚載明何方負責採購、測試及放行原物料、承擔生產及品質管制，含製程中管制，以及何方負責抽樣及檢驗。委託檢驗契約中應載明受託者是否應於製造者之廠房中取/抽樣。
7.13. Manufacturing, analytical and distribution records, and reference samples should be kept by, or be available to, the Contract Giver. Any records relevant to assessing the quality of a product in the event of complaints or a suspected defect must be accessible and specified in the defect/recall procedures of the Contract Giver.	7.13. 製造、檢驗及運銷之紀錄，以及對照樣品應由委託者保存，或可為委託者取得。當有申訴或懷疑有瑕疵時，應能取得與產品品質之評估有關的任何紀錄。這應明定於委託者之瑕疵/回收程序中。
7.14. The contract should permit the Contract Giver to visit the facilities of the Contract Acceptor.	7.14. 契約應明定容許委託者訪視受託者的廠房、設施、設備。
7.15. In case of contract analysis, the Contract Acceptor should understand that he is subject to inspection by the competent Authorities.	7.15. 在委/受託檢驗時，受託者應了解其應受主管機關的查核。

第八章　申訴和產品回收
（COMPLAINTS AND PRODUCT RECALL）

原則（PRINCIPLE）	
All complaints and other information concerning potentially defective products must be carefully reviewed according to written procedures. In order to provide for all contingencies, a system should be designed to recall, if necessary, promptly and effectively products known or suspected to be defective from the market.	一切申訴及其他與可能之瑕疵產品有關的資訊，均應遵循書載的程序詳實審核。為對一切意外事件作準備，應設計一套系統，以便在必要時，能立即且有效地自市場回收已知或懷疑其有瑕疵的產品。
申訴（COMPLAINTS）	
8.1. A person should be designated responsible for handling the complaints and deciding the measures to be taken together with sufficient supporting staff to assist him. If this person is not the authorised person, the latter should be made aware of any complaint, investigation or recall.	8.1. 應指定人員，並配以足夠的支援人員給予協助，以負責處理申訴及決定要採取的措施。該指定人員係非被授權人者，應使被授權人員知悉任何申訴、調查或回收事宜。
8.2. There should be written procedures describing the action to be taken, including the need to consider a recall, in the case of a complaint concerning a possible product defect.	8.2. 若涉及可能之產品瑕疵的申訴，應有書載的程序描述要採取的行動，包括考慮回收的需要。
8.3. Any complaint concerning a product defect should be recorded with all the original details and thoroughly investigated. The person responsible for Quality Control should normally be involved in the study of such problems.	8.3. 關於產品瑕疵的任何申訴，應記錄其全部原始細節並徹底調查。負責品質管制的人員通常應參與這些問題的研究。
8.4. If a product defect is discovered or suspected in a batch, consideration should be given to checking other batches should be checked in order to determine whether they are also affected. In particular, other batches which may contain reworks of the defective batch should be investigated.	8.4. 在任一批次中發現或懷疑有產品瑕疵時，應考慮檢查/核對其他批次的產品，以確定它們是否也受到影響。特別是，可能含有該瑕疵批次之再加工的其他批次應予調查。

8.5. All the decisions and measures taken as a result of a complaint should be recorded and referenced to the corresponding batch records.	8.5. 因申訴而做之決定與採取之措施應予記錄，並對照其對應的批次紀錄。
8.6. Complaints records should be reviewed regularly for any indication of specific or recurring problems requiring attention and possibly the recall of marketed products.	8.6. 申訴記錄應定期檢討，以發現需注意及可能應回收已上市產品之特定或再發性問題的任何跡象。
8.7. Special attention should be given to establishing whether a complaint was caused because of counterfeiting.	8.7. 應特別注意確立申訴是否因仿冒所引起。
8.8. The Competent Authorities should be informed if a manufacturer is considering action following possibly faulty manufacture, product deterioration, detection of counterfeiting or any other serious quality problems with a product.	8.8. 藥廠由於可能有瑕疵的製造、產品變質、仿冒之檢測或任何其他嚴重的產品品質問題，而考慮採取行動時，應通知主管機關。
回收（RECALLS）	
8.9. A person should be designated as responsible for execution and co-ordination of recalls and should be supported by sufficient staff to handle all the aspects of the recalls with the appropriate degree of urgency. This responsible person should normally be independent of the sales and marketing organisation. If this person is not the authorised person, the latter should be made aware of any recall operation.	8.9. 應指定人負責回收之執行與協調，並應給予足夠的支援人力，俾以適切迅速的程度處理一切回收事宜。該負責人通常應與銷售部門相互獨立。該負責人並非被授權人者，應使被授權人知悉任何回收作業。
8.10. There should be established written procedures, regularly checked and updated when necessary, in order to organise any recall activity.	8.10. 為有效組織任何回收作業，應建立書載的程序、定期檢查/核對，且於必要時，予以更新。
8.11. Recall operations should be capable of being initiated promptly and at any time.	8.11. 回收作業應能立即且在任何時候啟動。

8.12. All Competent Authorities of all countries to which products may have been distributed should be informed promptly if products are intended to be recalled because they are, or are suspected of, being defective.	8.12. 因產品有瑕疵或懷疑其有瑕疵，而要將其回收時，應立即通知可能已經對其運銷該產品之一切國家的主管機關。
8.13. The distribution records should be readily available to the person(s) responsible for recalls, and should contain sufficient information on wholesalers and directly supplied customers (with addresses, phone and/or fax numbers inside and outside working hours, batches and amounts delivered), including those for exported products and medical samples.	8.13. 運銷紀錄應易為負責回收的人取得，且應包含關於批發商和直銷客戶的充分資訊(連同地址、上、下班時間的電話/傳真號碼、送交的批次和數量)，包含輸出的產品和醫療用樣品在內。
8.14. Recalled products should be identified and stored separately in a secure area while awaiting a decision on their fate.	8.14. 回收的產品在等候決定其最終處置方式的期間，應予辨識並隔離儲存於安全區域。
8.15. The progress of the recall process should be recorded and a final report issued, including a reconciliation between the delivered and recovered quantities of the products.	8.15. 回收過程之進度應予記錄並提出最終報告。該報告應包含送交之產品與收回之產品的數量調和。
8.16. The effectiveness of the arrangements for recalls should be evaluated regularly.	8.16. 回收作業之安排的有效性應予定期評估。

第九章　自我查核（SELF INSPECTION）

原則（PRINCIPLE）	
Self inspections should be conducted in order to monitor the implementation and compliance wit（with） Good Manufacturing Practice principles and to propose necessary corrective measures.	為監測優良製造準則原則之實施與遵守，應執行自我查核，並就必要的矯正措施提出建議。
9.1. Personnel matters, premises, equipment, documentation, production, quality control, distribution of the medicinal products, arrangements for dealing with complaints and recalls, and self inspection, should be examined at intervals following a pre-arranged programme in order to verify their conformity with the principles of Quality Assurance.	9.1. 人事、廠房、設施、設備、文件、生產、品質管制、藥品的運銷、有關申訴與回收的安排，以及自我查核，皆應依預先安排之計畫的間隔時間進行檢查，以便證實其符合品質保證的原則。
9.2. Self inspections should be conducted in an independent and detailed way by designated competent person(s) from the company. Independent audits by external experts may also be useful.	9.2. 自我查核應由自公司指定之能勝任的人員，以獨立且詳細的方式來執行。外部專家的獨立稽核可能也是有用的。
9.3. All self inspections should be recorded. Reports should contain all the observations made during the inspections and, where applicable, proposals for corrective measures. Statements on the actions subsequently taken should also be recorded.	9.3. 一切自我查核應予記錄。報告應包含在檢查期間所從事之一切觀測，合適時，並含改正措施的建議。後來採取之行動的說明也應予記錄。

術語彙編 （GLOSSARY）

Definitions given below apply to the words as used in this Guide. They may have different meanings in other contexts.	下述定義適用於本準則使用的語詞。在其他文件背景中，這些語詞可能有不同的含義。
Action limit *Established criteria, requiring immediate follow-up and corrective action if exceeded.*	***行動限量*** *為已經建立的基準，如有超過時需要立即後續追蹤並執行改正行動。*
Air lock *An enclosed space with two or more doors, and which is interposed between two or more rooms, e.g. of differing class of cleanliness, for the purpose of controlling the air-flow between those rooms when they need to be entered. An air-lock is designed for and used by either people or goods.*	***氣鎖室*** *在介於例如不同潔淨度等級之兩個(含)以上作業室之間的具有兩個(含)以上門之一個密閉空間，其目的為在需要進入那些作業室時，管制其間的氣流。氣鎖室是為人員或物品進出所設計，並由人員或物品所使用。*
Alert limit *Established criteria giving early warning of potential drift from normal conditions which are not necessarily grounds for definitive corrective action but which require follow-up investigation.*	*為已經建立的基準，係在可能偏移正常條件時給予早期警告。該可能偏移未必是決定性改正行動的基礎/理由，但仍需要後續的追蹤調查。*
Authorised person *Person recognised by the authority as having the necessary basic scientific and technical background and experience.*	***被授權人*** *為經權責人員承認具有必需之基礎科學與技術背景及經驗的人。*
Batch (or lot) *A defined quantity of starting material, packaging material or product processed in one process or series of processes so that it could be expected to be homogeneous.*	***批/批次*** *在一個或一系列製程處理/加工之界定重量/數量的原料、包裝材料或產品，從而可預期其為均質的。*
Note： To complete certain stages of manufacture, it may be necessary to divide a batch into a number of subbatchs, which are later brought together to form a final homogeneous	*備註：為完成製造的某些階段，可能需要把一批次分成幾個次批次，而後再將其合併在一起，以構成一個最終的均質批次。在連續製造的情況，批次必須相當於由其預期的均質性表現特*

batch. In the case of continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity.	*徵，所界定之生產部分/時段的數量。*
For the control of the finished product, a batch of a medicinal products comprises all the units of a pharmaceutical form which are made from the same initial mass of material and have undergone a single series of manufacturing operations or a single sterilisation operation or, in the case of a continuous production process, all the units manufactured in a given period of time.	*為最終產品的管制，一批藥品是由同一初始原料之質量所製成劑型的全部單元所組成，且該批次係經歷一個單一系列的製造作業或一個單一滅菌作業，或在連續生產過程的情況，係在一定時段所製造的全部單元。*
Batch number (or lot number) *A distinctive combination of numbers and/or letters which specifically identifies a batch.*	***批號*** *明確辨識一個批次之數字及/或字母的獨特組合。*
Biogenerator *A contained system, such as a fermenter, into which biological agents are introduced along with other materials so as to effect their multiplication or their production of other substances by reaction with the other materials. Biogenerators are generally fitted with devices for regulation, control, connection, material addition and material withdrawal.*	***生物產生/滋生器（Biogenerator）*** *一種圍堵系統，例如醱酵槽，係將生物劑隨其他物質導入其內，以便經由與其他物質反應，啟動其繁殖或其生產其他物質。生物產生/滋生器通常套接其它裝置，以供調節、管制、連接、物質添加及物質提取。*
Biological agents *Microorganisms, including genetically engineered microorganisms, cell cultures and endoparasites, whether pathogenic or not.*	***生物劑*** *不管是致病性的或是非致病性的微生物(包括基因工程的微生物在內)、細胞培養物及胞內寄生物。*
Bulk product *Any product which has completed all processing stages up to, but not including, final packaging.*	***待分/包裝產品*** *已完成所有加工階段，但不包含最終包裝之任何產品。*
Calibration *The set of operations which establish, under*	***校正*** *指在規定條件下，建立由量測儀器或量測系*

specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a reference standard.	*統所指示數值、或由物質量度器所代表數值，與其對應之對照標準的已知數值間之關係的一套操作。*
Cell bank	***細胞庫***
Cell bank system: *A cell bank system is a system whereby successive batches of a product are manufactured by culture in cells derived from the same master cell bank (fully characterised for identity and absence of contamination). A number of containers from the master cell bank are used to prepare a working cell bank. The cell bank system is validated for a passage level or number of population doublings beyond that achieved during routine production*	***細胞庫系統：****係指一個細胞系統，藉由此系統之相同種源細胞庫（經充分表現其同一性及無污染特徵）所衍生之細胞的培養，用以製造產品之連續批次。來自種源細胞庫之若干容器用來製備一個工作細胞庫。該細胞庫系統，其超過例行生產期間所達成之繼代數或細胞加倍次數業經確效。*
Master cell bank*: A culture of (fully characterised) cells distributed into containers in a single operation, processed together in such a manner as to ensure uniformity and stored in such a manner as to ensure stability. A master cell bank is usually stored at -70°C or lower.*	***種源細胞庫：****經單次操作分裝成多個容器之一個充分表現其特徵的細胞培養物，以能確保其均一性之方式操作/加工/處理，並以能確保其安定性的方式儲存。種源細胞庫通常儲存在-70℃或更低。*
Working cell bank: *A culture of cells derived from the master cell bank and intended for use in the preparation of production cell cultures. The working cell bank is usually stored at -70°C or lower.*	***工作細胞庫/使用細胞庫：****從種源細胞庫所衍生之一個細胞培養物，預定用於製備生產用細胞培養物。工作細胞庫/使用細胞庫通常儲存在-70℃或更低。*
Cell culture *The result from the in-vitro growth of cells isolated from multicellular organisms.*	***細胞培養物*** *從來自多細胞生物體所分離之細胞的體外增殖之結果/產物。*
Clean area *An area with defined environmental control of particulate and microbial contamination, constructed and used in such a way as to reduce the introduction, generation and retention of contaminants within the area.*	***潔淨區*** *一個具有所界定之微粒與微生物污染的環境管制之區域，係以減低區域內污染物的導入、產生及滯留之方式建造與使用。*

Note: The different degrees of environmental control are defined in the Supplementary Guidelines for the Manufacture of sterile medicinal products.	*備註：不同程度之環境管制係界定於無菌藥品的製造之補充指引(即附則 1)中。*
Clean/contained area *An area constructed and operated in such a manner that will achieve the aims of both a clean area and a contained area at the same time.*	***潔淨/圍堵區*** *會同時達成潔淨區及圍堵區雙重目標所建造與運轉的區域。*
Containment *The action of confining a biological agent or other entity within a defined space.*	***圍堵*** *將生物劑或其他實體侷限在界定空間的行動。*
Primary containment: *A system of containment which prevents the escape of a biological agent into the immediate working environment. It involves the use of closed containers or safety biological cabinets along with secure operating procedures.*	***一級圍堵：****一種阻止生物劑散逸到緊鄰之作業區的圍堵系統。這包括使用密閉容器或生物安全櫃連同其確保安全的作業程序。*
Secondary containment: *A system of containment which prevents the escape of a biological agent into the external environment or into other working areas. It involves the use of rooms with specially designed air handling, the existence of airlocks and/or sterilises for the exit of materials and secure operating procedures. In many cases it may add to the effectiveness of primary containment.*	***次級圍堵：****一種阻止生物劑散逸到外部環境或其他作業區的圍堵系統。這包括使用具有特殊設計之空氣處理、供物質退出之氣鎖室及/或滅菌器，以及確保安全之作業程序等的作業室。在許多情況，這可用來增加一級圍堵的效果。*
Contained area *An area constructed and operated in such a manner (and equipped with appropriate air handling and filtration) so as to prevent contamination of the external environment by biological agents from within the area.*	***圍堵區*** *為避免外界環境受到來自此區域內之生物劑污染的方式所建造與運轉之區域(並配置適當的空氣處理及過濾裝置)。*
Controlled area *An area constructed and operated in such a*	***管制區*** *為管制潛在污染之導入(供應趨近 D 級的空*

manner that some attempt is made to control the introduction of potential contamination (an air supply approximating to grade D may be appropriate), and the consequences of accidental release of living organisms. The level of control exercised should reflect the nature of the organism employed in the process. At a minimum, the area should be maintained at a pressure negative to the immediate external environment and allow for the efficient removal of small quantities of airborne contaminants.	*氣應適當），及為管制活生物體之意外釋放的後果之方式，而意圖建造與運轉的一個區域。執行之管制的水準應反映該製程中使用之生物體的本質。該區域對緊鄰的外界環境至少應維持負壓，並允許有效移除小量浮游污染物。*
Computerised system *A system including the input of data, electronic processing and the output of information to be used either for reporting or automatic control.*	***電腦化系統*** *包含數據之輸入、電子處理及用於提報或自動控制用之資訊的輸出之系統。*
Cross contamination *Contamination of a starting material or of a product with another material or product.*	***交叉污染*** *一種原料或產品被另一種原料或產品所污染。*
Crude plant (vegetable drug) *Fresh or dried medicinal plant or parts thereof.*	***天然植物(植物藥)*** *新鮮的或乾燥的藥用植物或其部分。*
Cryogenic vessel *A container designed to contain liquefied gas at extremely low temperature.*	***低溫容器*** *為盛裝極低溫之液化氣體所設計的一種容器。*
Cylinder *A container designed to contain gas at a high pressure.*	***鋼瓶*** *為盛裝高壓氣體所設計的一種容器。*
Exotic organism *A biological agent where either the corresponding disease does not exist in a given country or geographical area, or where the disease is the subject of prophylactic measures or an eradication programme undertaken in the given country or geographical area.*	***異域生物體*** *一種生物劑，其對應的疾病不存在於一個特定的國家或地理區域，或該疾病是在該特定國家或地理區域所進行之預防措施或根除計畫的主題。*
Finished product	***最終產品***

A medicinal products which has undergone all stages of production, including packaging in its final container.	*已經歷生產之全部階段，包含分/包裝於其最終容器的藥品。*
Herbal medicinal products *Medicinal products containing, as active ingredients, exclusively plant material and/or vegetable drug preparations.*	***草本藥品*** *只含植物性材料及/或植物藥製劑為其有效成分的藥品。*
Infected *Contaminated with extraneous biological agents and therefore capable of spreading infection.*	***受感染的*** *受外在生物劑所污染，且因此具有傳染(散佈感染)的能力。*
In-process control *Checks performed during production in order to monitor and if necessary to adjust the process to ensure that the product conforms to its specification. The control of the environment or equipment may also be regarded as a part of in-process control.*	***製程中管制*** *在生產期間執行的檢查，以監視及在必要時調整該製程，以確保產品符合其規格。環境或設備的管制也可被視為製程中管制的一部分。*
Intermediate product *Partly processed material which must undergo further manufacturing steps before it becomes a bulk product.*	***半製品/中間產品*** *經部分加工的原料，在其變成待分/包裝產品之前，還須經進一步的製造步驟。*
Liquifiable gases *Those which, at the normal filling temperature and pressure, remain as a liquid in the cylinder.*	***可液化的氣體*** *在正常充填溫度及壓力下，在鋼瓶中保持液態的氣體。*
Manifold *Equipment or apparatus designed to enable one or more gas containers to be filled simultaneously from the same source.*	***歧管*** *為使一個或多個氣體容器能從相同來源同時充填，而設計的設備或裝置。*
Manufacture *All operations of purchase of materials and products, Production, Quality Control, release, storage, distribution of medicinal products and the related controls.*	***製造*** *藥品的原物料與產品/製品的採購、生產、品質管制、放行、儲存、運銷及相關管制等的一切作業。*

Manufacturer *Holder of a manufacturing authorization.*	***藥廠/製造廠/製造者*** *製造許可的持有者。*
Media fill *Method of evaluating an aseptic process using a microbial growth medium. (Media fills are synonymous to simulated product fills, broth trials, broth fills etc.).*	***培養基充填*** *使用一種微生物生長培養基為評估無菌製程的方法。（培養基充填是與模擬產品充填、液體培養基試驗、液體培養基充填等的同義詞）。*
Medicinal plant *Plant the whole or part of which is used for pharmaceutical purpose.*	***藥用植物*** *供藥用目的使用之植物的全株或其部分。*
Medicinal products *Any medicine or similar product intended for human use, which is subject to control under health legislation in the manufacturing or importing State.*	***藥用產品/藥品*** *受製造國或進口國之衛生法規管制的預定供人用之任何藥品或相似的產品。*
Packaging *All operations, including filling and labelling, which a bulk product has to undergo in order to become a finished product.*	***分/包裝*** *為將待分/包裝產品變成最終產品所必須進行的一切作業，包含充填及標示在內。*
Note: Sterile filling would not normally be regarded as part of packaging, the bulk product being the filled, but not finally packaged, primary containers.	*備註：無菌充填通常不被視為分/包裝的一部分；待分/包裝產品是指已充填於直接容器，但尚未執行最終包裝的產品。*
Packaging material *Any material employed in the packaging of a medicinal products, excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.*	***包裝材料*** *在藥品分/包裝上使用的任何材料，但不包含為輸送或裝運而使用的外包裝材料。包裝材料按其是否擬供與產品直接接觸，分別被歸為直接或非直接包裝材料。*
Procedures *Description of the operations to be carried out, the precautions to be taken and measures to be*	***程序*** *直接或間接與一種藥品之製造有關的所要執行之作業、所要採取之預防事項及所要應*

applied directly or indirectly related to the manufacture of a medicinal products.	*用之措施的描述。*
Production *All operations involved in the preparation of a medicinal products, from receipt of materials, through processing and packaging, to its completion as a finished product.*	***生產*** *在藥品的製備上，從原物料的接收，經加工及分/包裝到最終產品之完成所牽涉的一切作業。*
Qualification *Action of proving that any equipment works correctly and actually leads to the expected results. The word validation is sometimes widened to incorporate the concept of qualification.*	***驗證*** *證明任何設備皆正確運轉並實際導引到預定結果的行動。確效一詞有時擴及納入驗證的觀念。*
Quality control *See Chapter* ***1.***	***品質管制*** *參見第一章。*
Quarantine *The status of starting or packaging materials, intermediate, bulk or finished products isolated physically or by other effective means whilst awaiting a decision on their release or refusal.*	***隔離/待驗*** *原料或包裝材料、半製品/中間產品、待分/包裝產品或最終產品，在等候放行或拒用的決定時，以實體或經由其他有效方法隔離的狀態。*
Radiopharmaceutical *"Radiopharmaceutical" means any medicinal products which, when ready for use , contains one or more radionuclides (radioactive isotopes) included for a pharmaceutical purpose.*	***放射性藥品*** *當可供使用時，"放射性藥品"意指為藥用目的而含有一種或多種放射性核種（放射性同位素）的任何一種藥品。*
Reconciliation *A comparison, making due allowance for normal variation, between the amount of product or materials theoretically and actually produced or used.*	***數量/重量調和*** *在考慮正常變異之適當容許量下，對產出或使用之產品或原物料的理論量與實際量間的比較。*
Record *See Chapter 4.*	***紀錄/記錄*** *參見第四章。*

Recovery *The introduction of all or part of previous batches of the required quality into another batch at a defined stage of manufacture.*	***收回*** *係指在一個界定之製造階段，將符合要求品質之先前批次的全部或一部分加入另一批次中。*
Reprocessing *The reworking of all or part of a batch of product of an unacceptable quality from a defined stage of production so that its quality may be rendered acceptable by one or more additional operations.*	***重製/重處理*** *對來自一個界定之生產階段的不符合品質之一批產品的全部或部分，藉一個或以上追加作業之再加工，以使其品質變成可接受。*
Return *Sending back to the manufacturer or distributor of a medicinal products which may or may not present a quality defect.*	***退回*** *將可能呈現或無呈現品質瑕疵的藥品，送回製藥廠或經銷商。*
Seed lot	***種批***
Seed lot system: *A seed lot system is a system according to which successive batches of a product are derived from the same master seed lot at a given passage level. For routine production, a working seed lot is prepared from the master seed lot. The final product is derived from the working seed lot and has not undergone more passages from the master seed lot than the vaccine shown in clinical studies to be satisfactory with respect to safety and efficacy. The origin and the passage history of the master seed lot and the working seed lot are recorded.*	***種批系統：****種批系統是一個系統。依該系統，一個產品之連續批次係衍生自已知繼代數的同一主種批。對於例行生產，一個工作種批係從主種批所製備。最終產品係衍生自工作種批，且其自主種批起算之繼代數，未超過為滿足安全性及有效性之臨床試驗的疫苗所顯示者。主種批及工作種批之起源及繼代歷史應予記錄。*
Master seed lot: *A culture of a micro-organism distributed from a single bulk into containers in a single operation in such a manner as to ensure uniformity, to prevent contamination and to ensure stability. A master seed lot in liquid form is usually stored at or below -70°C. A freeze-dried master seed lot is stored at a temperature known to ensure stability.*	***主種批：****在確保均一性、防止污染及確保安定性的方式下，以單次操作，從單一的培養液分裝成多個容器中之微生物培養物。液態型式的主種批通常是儲存在-70℃以下。冷凍乾燥型式的主種批是儲存在一已知能確保其安定性的溫度。*

Working seed lot: *A culture of a micro-organism derived from the master seed lot and intended for use in production. Working seed lots are distributed into containers and stored as described above for master seed lots.*	***工作種批：****從主種批衍生，且擬供生產使用之一種微生物培養物。工作種批分裝成多個容器中，並依照對主種批之上面描述的方法儲存。*
Specification *See Chapter 4.*	***規格*** *參見第四章。*
Starting material *Any substance used in the production of a medicinal products, but excluding packaging materials.* 【建議】(原文 *a medicinal products* 文法錯誤)	***原料*** *藥品之生產中所使用的任何物質，但不含包裝材料。*
Sterility *Sterility is the absence of living organisms. The conditions of the sterility tests are given in the European or other relevant Pharmacopoeia.**	***無菌性*** *無菌性指無活的生物體存在。無菌性試驗的條件收載於歐洲藥典或其他相關的藥典中。** *(應改為：無菌性試驗的條件收載於中華藥典或其他相關的藥典中)*
**The procedures and precautions employed should be such as to give a theoretical level of not more than one living micro-organism in 10^6 units in the final product.*	**採用的程序及預防措施，應使每一百萬（10^6）個單元最終產品中活微生物不超過 1 個的理論水準。*
Validation *Action of proving, in accordance with the principles of Good Manufacturing Practice, that any procedure, process, equipment, material, activity or system actually leads to the expected results (see also qualification).*	***確效*** *依照藥品優良製造準則的原則，證明任何程序、製程、設備、原物料、活動或系統真實地導引到預期之結果的行動（亦參見驗證項目）。*