西藥藥品優良製造規範
（第一部）

PIC/S：Guide to Good Manufacturing Practice for Medicinal Products
（Part I）

PE009-13 (1 January 2017)

第一部（Part I）

目　錄

第一章 製藥品質系統（PHARMACEUTICAL QUALITY SYSTEM）

原則（PRINCIPLE）	
製造許可的持有者製造藥品時，應確保該藥品適合其預定用途，符合上市許可或符合臨床試驗許可（合適時）的要求，且不會由於其安全性、品質或有效性的不足而使病人陷於危險。該品質目標之達成是高層管理者的責任，且需要公司內各部門及所有階層之人員，以及公司之供應商與經銷商的參與和許諾。為可靠達成該品質目標，應有全面設計並正確實施的製藥品質系統。該系統涵蓋優良製造規範及品質風險管理，應充分文件化，並監測其效果。製藥品質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另有其他法律責任。	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 or Clinical Trial Authorisation, as appropriate, 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 its distributors. To achieve this quality objective reliably there must be a comprehensively designed and correctly implemented Pharmaceutical Quality System incorporating Good Manufacturing Practice and Quality Risk Management. It should be fully documented and its effectiveness monitored. All parts of the Pharmaceutical Quality System 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 Authorisation and for the Authorised Person(s).

品質管理、優良製造規範及品質風險管理的基本概念是相互關聯的。在本章中予以描述，以強調其間之關係及其對於藥品生產及管制之基本的重要性。	The basic concepts of Quality Management, Good Manufacturing Practice (GMP) and Quality Risk Management are inter-related. They are described here in order to emphasise their relationships and their fundamental importance to the production and control of medicinal products.
製藥品質系統[1]（PHARMACEUTICAL QUALITY SYSTEM[1]）	
[1] 製造廠須建立並執行有效的「製藥品質保證系統」。「製藥品質系統」一詞用於本章係與 ICH Q10 術語一致，為了本章的目的，此等術語可視為可互換的。	[1] National requirements require to establish and implement an effective pharmaceutical quality assurance system. The term Pharmaceutical Quality System is used in this chapter in the interests of consistency with ICH Q10 terminology. For the purposes of this chapter these terms can be considered interchangeable.
1.1 品質管理是一個廣泛的概念。該概念涵蓋單獨或共同影響產品品質的所有事項。品質管理是經組織之安排的總和，以確保藥品具有預定用途所需之品質。因此，將優良製造規範納入品質管理。	1.1 Quality Management 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 objective of ensuring that medicinal products are of the quality required for their intended use. Quality Management therefore incorporates Good Manufacturing Practice.

1.2	GMP 適用於從研究用藥品的製造、技術移轉、商業製造到產品終止的生命週期階段。但是，如同 ICH Q10 所描述，製藥品質系統可以延伸到製藥開發生命週期階段，雖然其為可選擇的項目，但應會促進創新與持續改善，並且強化製劑開發與製造活動之間的持續連結。	1.2	GMP applies to the lifecycle stages from the manufacture of investigational medicinal products, technology transfer, commercial manufacturing through to product discontinuation. However the Pharmaceutical Quality System can extend to the pharmaceutical development lifecycle stage as described in ICH Q10, which while optional, should facilitate innovation and continual improvement and strengthen the link between pharmaceutical development and manufacturing activities.
1.3	當開發新的製藥品質系統或修改既有的系統時，應考慮公司的規模與複雜性。系統的設計應納入適當的風險管理原則，包含適當工具的使用在內。雖然系統的某些層面是涵蓋全公司的，而其他層面是製藥場所專一的，但製藥品質系統的有效性通常是在製藥場所層級加以證明之。	1.3	The size and complexity of the company's activities should be taken into consideration when developing a new Pharmaceutical Quality System or modifying an existing one. The design of the system should incorporate appropriate risk management principles including the use of appropriate tools. While some aspects of the system can be company-wide and others site-specific, the effectiveness of the system is normally demonstrated at the site level.
1.4	適合藥品製造的製藥品質系統應確保下列事項：	1.4	A Pharmaceutical Quality System appropriate for the manufacture of medicinal products should ensure that:
	(i) 產品實現是經由設計、規劃、執行、維持與持續改進之系統所達成，以允許持續地產出具有適當品質屬性的產品；		(i) Product realisation is achieved by designing, planning, implementing, maintaining and continuously improving a system that allows the consistent delivery of products with appropriate quality attributes;

(ii) 產品與製程知識在生命週期的所有階段皆加以管理；	(ii) Product and process knowledge is managed throughout all lifecycle stages;
(iii) 藥品之設計與開發方式應考慮優良製造規範的要求；	(iii) Medicinal products are designed and developed in a way that takes account of the requirements of Good Manufacturing Practice;
(iv) 生產和管制作業應予清楚界定，並採用優良製造規範；	(iv) Production and control operations are clearly specified and Good Manufacturing Practice adopted;
(v) 管理責任應予清楚界定；	(v) Managerial responsibilities are clearly specified;
(vi) 為正確之原料與包裝材料的製造、供應與使用、供應商的選擇與監督，以及為確認每次交貨都是來自經核准的供應鏈等進行安排；	(vi) Arrangements are made for the manufacture, supply and use of the correct starting and packaging materials, the selection and monitoring of suppliers and for verifying that each delivery is from the approved supply chain;
(vii) 具備程序，以確保委外活動的管理；	(vii) Processes are in place to assure the management of outsourced activities;
(viii) 經由開發及使用有效的監測與管控系統，對製程性能與產品品質建立並維持管制的狀態；	(viii) A state of control is established and maintained by developing and using effective monitoring and control systems for process performance and product quality;
(ix) 在批次放行及在偏差的調查中，應考慮產品與製程監測的結果，並採取預防行動，以避免在未來發生潛在的偏差；	(ix) The results of product and processes monitoring are taken into account in batch release, in the investigation of deviations, and, with a view to taking preventive action to avoid potential deviations occurring in the future;
(x) 半製品/中間產品的所有必要管制，以及任何其他製程中管制與確效均已執行；	(x) All necessary controls on intermediate products, and any other in-process controls and validations are carried out;

(xi) 經由適合現行製程與產品知識水準之品質改善的實施，促進持續改善；	(xi) Continual improvement is facilitated through the implementation of quality improvements appropriate to the current level of process and product knowledge;
(xii) 考慮法規管理的通報與核准（需要時），對於計劃性變更的先期性評估及其實施前的核准，具有適當的安排；	(xii) Arrangements are in place for the prospective evaluation of planned changes and their approval prior to implementation taking into account regulatory notification and approval where required;
(xiii) 在任何變更實施之後進行評估，以確認達成品質目標，並且對產品品質沒有非預期的不良影響；	(xiii) After implementation of any change, an evaluation is undertaken to confirm the quality objectives were achieved and that there was no unintended deleterious impact on product quality;
(xiv) 在偏差、質疑的產品缺陷與其他問題的調查上，應使用適當程度的根本原因分析。	(xiv) An appropriate level of root cause analysis should be applied during the investigation of deviations, suspected product defects and other problems.

這可採品質風險管理原則予以確定之。若問題的真正根本原因不能確定時，則應考慮辨別最可能的根本原因，並解決該等問題。在懷疑或確認人為錯誤為其原因時，應證明其合理性，以確保未曾忽略製程、程序或基於系統的錯誤或問題（若存在時）。應確認並採取適當的矯正行動與預防行動以回應其調查，該行動的有效性應根據品質風險管理原則加以監測與評估；	This can be determined using Quality Risk Management principles. In cases where the true root cause(s) of the issue cannot be determined, consideration should be given to identifying the most likely root cause(s) and to addressing those. Where human error is suspected or identified as the cause, this should be justified having taken care to ensure that process, procedural or system based errors or problems have not been overlooked, if present. Appropriate corrective actions and/or preventive actions (CAPAs) should be identified and taken in response to investigations. The effectiveness of such actions should be monitored and assessed, in line with Quality Risk Management principles;
(xv) 未經被授權人認可每一生產批次皆已依上市許可及任何有關藥品之生產、管制及放行的法規之要求生產與管制前，該藥品不得銷售或供應；	(xv) 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 Marketing Authorisation and any other regulations relevant to the production, control and release of medicinal products;

	(xvi) 藥品之儲存、運銷及後續的處理應有妥善的安排，以確保在架儲期間能維持其品質；		(xvi) 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;
	(xvii) 有自我查核及/或品質稽查的程序，以定期評估製藥品質系統之有效性及適用性。		(xvii) There is a process for self-inspection and/or quality audit, which regularly appraises the effectiveness and applicability of the Pharmaceutical Quality System.
1.5	高層管理者對確保具備充分資源配置之有效的製藥品質系統，並在整個組織中界定、溝通與執行角色、職責與權力，具有最終責任。高層管理者的領導與主動參與製藥品質系統是至關重要的，此領導應確保在組織內的所有階層與製藥場所的工作人員對該製藥品質系統的支持與承諾。	1.5	Senior management has the ultimate responsibility to ensure an effective Pharmaceutical Quality System is in place, adequately resourced and that roles, responsibilities, and authorities are defined, communicated and implemented throughout the organisation. Senior management's leadership and active participation in the Pharmaceutical Quality System is essential. This leadership should ensure the support and commitment of staff at all levels and sites within the organisation to the Pharmaceutical Quality System.
1.6	製藥品質系統之運作應有定期管理審查，並有高層管理者參與，以確認對於產品、製程與系統本身的持續改善機會。	1.6	There should be periodic management review, with the involvement of senior management, of the operation of the Pharmaceutical Quality System to identify opportunities for continual improvement of products, processes and the system itself.

1.7 製藥品質系統應加以界定並文件化。應建立品質手冊或其他等同之文件，並且應含有包括管理人員職責在內之品質管理系統的描述。	1.7 The Pharmaceutical Quality System should be defined and documented. A Quality Manual or equivalent documentation should be established and should contain a description of the quality management system including management responsibilities.
藥品優良製造規範（GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS）	
1.8 優良製造規範（GMP）係品質管理的一部分，用以確保藥品一致地生產及管制，以達到適合其預定用途及如同上市許可、臨床試驗許可或產品規格所要求之品質標準。優良製造規範是與生產及品質管制兩者有關，其基本要求為：	1.8 Good Manufacturing Practice is that part of Quality Management 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, Clinical Trial Authorisation or product specification. Good Manufacturing Practice is concerned with both production and quality control. The basic requirements of GMP are that:
(i) 所有製造過程均已清楚地界定，按照經驗有系統地檢討，顯示其能一致地製造所要求之品質並符合其規格的藥品；	(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;
(ii) 製程的關鍵步驟及對製程的重大變更業經確效；	(ii) Critical steps of manufacturing processes and significant changes to the process are validated;
(iii) 提供優良製造規範所需之資源包括：	(iii) All necessary facilities for GMP are provided including:
● 經適當資格檢定與訓練的人員；	● Appropriately qualified and trained personnel;
● 足夠的廠房與作業空間；	● Adequate premises and space;

● 適當的設備及支援服務；	● Suitable equipment and services;
● 正確的原物料、容器及標籤；	● Correct materials, containers and labels;
● 依製藥品質系統所核定之程序及指令；	● Approved procedures and instructions, in accordance with the Pharmaceutical Quality System;
● 適當之儲存及運送。	● Suitable storage and transport.
(iv) 以清楚且不含糊的表達方式，將指令及程序書寫成指導性的型式。這特別適用於提供的資源；	(iv) Instructions and procedures are written in an instructional form in clear and unambiguous language, specifically applicable to the facilities provided;
(v) 程序被正確地執行，其操作者並經訓練；	(v) Procedures are carried out correctly and operators are trained to do so;
(vi) 製造過程中，以手寫及/或記錄儀器所作紀錄，證明界定的程序與指令所要求之所有步驟皆已實際執行，且產品的數量與品質皆如所預期；	(vi) Records are made, manually 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;
(vii) 任何顯著的偏差均完整地記錄，並以確定根本原因為目標進行調查，並實施適當的矯正與預防行動；	(vii) Any significant deviations are fully recorded, investigated with the objective of determining the root cause and appropriate corrective and preventive action implemented;
(viii) 包含運銷在內之製造紀錄，應以可理解及可取得的形式保存，以利追溯批次之完整歷程；	(viii) Records of manufacture including distribution which enable the complete history of a batch to be traced are retained in a comprehensible and accessible form;

(ix) 產品的運銷應使其對於產品品質的任何風險降到最低，並考慮優良運銷規範；	(ix) The distribution of the products minimises any risk to their quality and takes account of good distribution practice;
(x) 應有一套自銷售或供應點回收任何批次產品之系統；	(x) A system is available to recall any batch of product, from sale or supply;
(xi) 審查關於產品的申訴，調查品質瑕疵的原因，且對於該瑕疵產品採取適當的措施，以防止其再度發生。	(xi) Complaints about products are examined, the causes of quality defects investigated and appropriate measures taken in respect of the defective products and to prevent reoccurrence.
品質管制（QUALITY CONTROL）	
1.9 品質管制是優良製造規範的一部分，涉及抽樣、規格及檢驗，且與組織、文件與放行程序有關，用以確保必要且相關的試驗已確實執行，並確保品質判定合格前，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：	1.9 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:
(i) 具有適當的設施、受過訓練的人員及經認可的程序，以供抽樣和檢驗原料、包裝材料、半製品/中間產品、待分/包裝產品及最終產品，並於適當時為優良製造規範之目的監測環境條件；	(i) Adequate facilities, trained personnel and approved procedures are available for sampling and testing starting materials, packaging materials, intermediate, bulk, and finished products, and where appropriate for monitoring environmental conditions for GMP purposes;

(ii) 原料、包裝材料、半製品/中間產品、待分/包裝產品及最終產品的樣品應經核准的人員及方法抽取之；	(ii) Samples of starting materials, packaging materials, intermediate products, bulk products and finished products are taken by approved personnel and methods;
(iii) 檢驗方法業經確效；	(iii) Test methods are validated;
(iv) 應以手寫及/或記錄儀器製作紀錄，證明所有要求的抽樣、檢查及檢驗程序皆已實際執行。任何偏差均完整記錄並經調查；	(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;
(v) 含符合上市許可或臨床試驗許可的定性與定量組成之有效成分的最終產品，應符合所要求之純度，且密封在適當容器內，並正確地標示；	(v) The finished products contain active ingredients complying with the qualitative and quantitative composition of the Marketing Authorisation or Clinical Trial Authorisation, are of the purity required, and are enclosed within their proper containers and correctly labelled;
(vi) 原物料、半製品/中間產品、待分/包裝產品及最終產品的檢查與檢驗結果均應予記錄，並對照其規格正式評估之。產品評價包含相關生產文件的審核與評估，以及與規定程序偏差的評價；	(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;
(vii) 每批產品，非經被授權人認可符合相關許可之要求，不得放行銷售或供應；	(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 relevant authorisations;

(viii) 依照附則 19，應保留足夠的原料與產品的對照樣品，以容許未來必要時對該產品的檢查與檢驗，而且該樣品應保留在其最終包裝中。	(viii) Sufficient reference samples of starting materials and products are retained in accordance with Annex 19 to permit future examination of the product if necessary and that the sample is retained in the final pack.
產品品質檢討（PRODUCT QUALITY REVIEW）	
1.10 所有經許可的藥品，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，以凸顯任何趨勢並確認產品與製程之改善事項。前述之檢討通常應每年執行一次並加以文件化，並考量先前之檢討，且至少包含下列項目：	1.10 Regular periodic or rolling quality reviews of all authorised 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. Such reviews should normally be conducted and documented annually, taking into account previous reviews, and should include at least:
(i) 用於產品之原料及包裝材料，特別是那些來自新來源者之檢討，尤其是原料藥供應鏈之可追溯性的檢討；	(i) A review of starting materials including packaging materials used in the product, especially those from new sources and in particular the review of supply chain traceability of active substances;
(ii) 關鍵之製程中管制及最終產品結果的檢討；	(ii) A review of critical in-process controls and finished product results;
(iii) 不符合既定規格的所有批次及其調查之檢討；	(iii) A review of all batches that failed to meet established specification(s) and their investigation;

(iv) 所有顯著的偏差或不符合、其相關的調查及採取的矯正預防措施效果之檢討；	(iv) A review of all significant deviations or non-conformances, their related investigations, and the effectiveness of resultant corrective and preventive actions taken;
(v) 製程或分析方法所有變更之檢討；	(v) A review of all changes carried out to the processes or analytical methods;
(vi) 上市許可變更所提交/核准/否准文件之檢討，包含外銷專用文件在內；	(vi) A review of Marketing Authorisation variations submitted, granted or refused, including those for third country (export only) dossiers;
(vii) 安定性監測計畫的結果及任何不良趨勢之檢討；	(vii) A review of the results of the stability monitoring programme and any adverse trends;
(viii) 所有與品質相關之退回、申訴、回收及當時所執行調查之檢討；	(viii) A review of all quality-related returns, complaints and recalls and the investigations performed at the time;
(ix) 任何其他先前產品製程或設備矯正措施適當性之檢討；	(ix) A review of adequacy of any other previous product process or equipment corrective actions;
(x) 為新上市許可及變更上市許可所做之上市後許諾之檢討；	(x) For new Marketing Authorisations and variations to Marketing Authorisations, a review of post-marketing commitments;
(xi) 相關設備與公用設施，例如，空調系統（HVAC）、水系統、壓縮氣體等的驗證狀態；	(xi) The qualification status of relevant equipment and utilities, e.g. HVAC, water, compressed gases, etc;
(xii) 如同在第七章所界定之任何合約安排的檢討，確保其為最新。	(xii) A review of any contractual arrangements as defined in Chapter 7 to ensure that they are up to date.

1.11 在製藥品質系統下，製造者與上市許可持有者不同時，雙方應評估本檢討的結果，而且應評估是否採取矯正預防措施或任何再確效。對於持續進行之管理及這些行動的檢討應有管理程序，且在自我查核期間應證明這些程序之有效性。當符合科學正當性時，品質檢討得按其產品類型，例如固體劑型、液體劑型、無菌製劑等予以分組。	1.11 The manufacturer and, where different, Marketing Authorisation holder should evaluate the results of the review and an assessment made as to whether corrective and preventive action or any revalidation should be undertaken, under the Pharmaceutical Quality System. 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.
若上市許可持有者不是製造者時，雙方應有一份界定其各自在產品品質檢討上所負職責之技術協議書。負責批次之最終核定的被授權人與上市許可持有者應確保品質檢討係適時執行且為準確的。	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 product 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.
品質風險管理（QUALITY RISK MANAGEMENT）	
1.12 品質風險管理是針對藥品品質風險之評價、管制、溝通及檢討的系統過程。可用前瞻性及回溯性的方式來執行。	1.12 Quality Risk Management is a systematic process for the assessment, control, communication and review of risks to the quality of the medicinal product. It can be applied both proactively and retrospectively.
1.13 品質風險管理的原則為：	1.13 The principles of Quality Risk Management are that:

(i) 品質風險的評估是基於科學知識、製程的經驗，最終並連結至病患之保護；	(i) The evaluation of the risk to quality is based on scientific knowledge, experience with the process and ultimately links to the protection of the patient;
(ii) 品質風險管理過程的努力、正式化及文件化之程度應與風險程度相稱。	(ii) The level of effort, formality and documentation of the Quality Risk Management process is commensurate with the level of risk.
此外，品質風險管理之過程及應用的實例詳見附則 20 或 ICH Q9。	Examples of the processes and applications of Quality Risk Management can be found inter alia in Annex 20 or ICHQ9.

第二章　組織與人事（PERSONNEL）

原則（PRINCIPLE）	
藥品的正確製造仰賴於人。因此，藥廠有責任配置足夠的合格人員。個別工作人員應清楚瞭解其負責之工作並作成紀錄。所有人員均應認知優良製造規範的原則與其息息相關，並接受職前及持續的訓練，包括與工作有關的衛生指導。	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.
一般規定（GENERAL）	
2.1　藥廠應配置足夠人員，且具必要資格及實務經驗。高層管理者應決定並提供充足與適當的資源（人員、財務、物資、設施及設備等）以執行及維持製藥品質系統，且持續地改進其有效性。賦予每一個人的責任不應過廣，以致對於品質呈現任何風險。	2.1　The manufacturer should have an adequate number of personnel with the necessary qualifications and practical experience. Senior management should determine and provide adequate and appropriate resources (human, financial, materials, facilities and equipment) to implement and maintain the Pharmaceutical Quality System and continually improve its effectiveness. The responsibilities placed on any one individual should not be so extensive as to present any risk to quality.
2.2　藥廠應有組織圖，其中，生產、品管主管與合適時 2.5 條所提及之品質保證或品質單位主管之間的關係，及被授權人的位置，應清楚地顯示於其管理架構中。	2.2　The manufacturer must have an organisation chart in which the relationships between the heads of Production, Quality Control and where applicable Head of Quality Assurance or Quality Unit referred to in point 2.5 and the position of the Authorised Person(s) are clearly shown in the managerial hierarchy.

2.3	各職位的負責人應有書面工作說明記載的特定職責，並經適當授權，以執行其職責。其職責得委由足以勝任的指定代理人行之。適用優良製造規範之有關人員，其職責不應有漏洞或未經說明的重疊。	2.3	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.
2.4	高層管理者對於確保具備有效的製藥品質系統以達成品質目標，以及人員之角色與權責在整個組織中被界定、傳達與執行，具有最終責任。高層管理者應建立一個品質政策，描述公司與品質相關之整體意圖與方向，並且應透過參與管理審查，確保製藥品質系統與 GMP 循規的持續適用性與有效性。	2.4	Senior management has the ultimate responsibility to ensure an effective Pharmaceutical Quality System is in place to achieve the quality objectives, and, that roles, responsibilities, and authorities are defined, communicated and implemented throughout the organisation. Senior management should establish a quality policy that describes the overall intentions and direction of the company related to quality and should ensure continuing suitability and effectiveness of the Pharmaceutical Quality System and GMP compliance through participation in management review.
關鍵人員（KEY PERSONNEL）			

2.5 高層管理者應任命關鍵管理人員，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 2.7、2.8 及 2.9 條中所列之部分職務。另外，根據公司之規模與組織架構，可指派個別的品質保證主管或品質單位主管；若該職務存在時，於 2.7、2.8 與 2.9 條中所描述的職責，有部分是與品質管制主管及生產主管分擔的，因此高層管理者應謹慎界定其角色與權責。	2.5 Senior Management should appoint Key Management Personnel including 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 2.7, 2.8 and 2.9. Additionally, depending on the size and organisational structure of the company, a separate Head of Quality Assurance or Head of the Quality Unit may be appointed. Where such a function exists usually some of the responsibilities described in 2.7, 2.8 and 2.9 are shared with the Head of Quality Control and Head of Production and senior management should therefore take care that roles, responsibilities, and authorities are defined.
2.6 被授權人之職責可歸納如下：	2.6 The duties of the Authorised Person(s) are described in the national requirements and can be summarised as follows:
a) 被授權人必須確保每一批次藥品已遵循國家有效法律及依照上市許可的要求進行製造與檢查；	a) An Authorised Person must ensure that each batch of medicinal products has been manufactured and checked in compliance with the laws in force in that country and in accordance with the requirements of the Marketing Authorisation;

b) 被授權人必須符合法規的資格要求，他們須在製造許可持有者指派下持續地履行其職責；	b) The Authorised Person(s) must meet the qualification requirements laid down in the national legislation, they shall be permanently and continuously at the disposal of the holder of the Manufacturing Authorisation to carry out their responsibilities;
c) 被授權人之職責可以進行委派，但僅限於另一位被授權人。	c) The responsibilities of an Authorised Person may be delegated, but only to other Authorised Person(s).
2.7 生產部門的主管通常有下列職責：	2.7 The head of Production generally has the following responsibilities:
(i) 為獲得要求的品質，應確保該等產品依適當的文件生產與儲存；	(i) To ensure that products are produced and stored according to the appropriate documentation in order to obtain the required quality;
(ii) 核准與生產作業有關的指令，並確保其嚴格的實施；	(ii) To approve the instructions relating to production operations and to ensure their strict implementation;
(iii) 確保生產紀錄已由經授權的人員評估與簽章；	(iii) To ensure that the production records are evaluated and signed by an authorised person;
(iv) 確保其部門、廠房設施與設備的驗證及維護保養；	(iv) To ensure the qualification and maintenance of his department, premises and equipment;
(v) 確保已完成適當的確效；	(v) To ensure that the appropriate validations are done;
(vi) 確保其部門的人員已執行所要求的職前與持續訓練，並依需求進行調適。	(vi) To ensure that the required initial and continuing training of his department personnel is carried out and adapted according to need.
2.8 品質管制的主管通常有下列職責：	2.8 The head of Quality Control generally has the following responsibilities:

	(i) 合適時，核准或拒用原料、包裝材料、半製品/中間產品、待分/包裝產品及最終產品；		(i) To approve or reject, as he/she sees fit, starting materials, packaging materials, intermediate, bulk and finished products;
	(ii) 確保已執行所有必要的試驗，且相關紀錄也已進行評估；		(ii) To ensure that all necessary testing is carried out and the associated records evaluated;
	(iii) 核准規格、抽樣指令、檢驗方法及其他品質管制程序；		(iii) To approve specifications, sampling instructions, test methods and other Quality Control procedures;
	(iv) 受託檢驗者之核准及監督；		(iv) To approve and monitor any contract analysts;
	(v) 確保其部門、廠房設施與設備的驗證及維護保養；		(v) To ensure the qualification and maintenance of his/her department, premises and equipment;
	(vi) 確保已完成適當的確效；		(vi) To ensure that the appropriate validations are done;
	(vii) 確保其部門的人員已執行所要求的職前與持續訓練，並依需求進行調適。		(vii) To ensure that the required initial and continuing training of his department personnel is carried out and adapted according to need.
	品質管制部門的其他職責概述於第六章。		Other duties of Quality Control are summarised in Chapter 6.
2.9	生產和品質管制的主管，以及相關時品質保證主管或品質單位主管，通常有一些分擔或共同負擔之關於品質的職責，特別包括製藥品質系統之設計、有效實施、監測與維護。這些職責應受任何國家法規的規範，包括：	2.9	The heads of Production, Quality Control and where relevant, Head of Quality Assurance or Head of Quality Unit, generally have some shared, or jointly exercised, responsibilities relating to quality including in particular the design, effective implementation, monitoring and maintenance of the Pharmaceutical Quality System. These may include, subject to any national regulations:

(i) 書面的程序和其他文件的認可，包括修訂在內；	(i) The authorisation of written procedures and other documents, including amendments;
(ii) 製造環境的監測與管制；	(ii) The monitoring and control of the manufacturing environment;
(iii) 工廠衛生；	(iii) Plant hygiene;
(iv) 製程確效；	(iv) Process validation;
(v) 訓練；	(v) Training;
(vi) 原物料供應商的認可及監督；	(vi) The approval and monitoring of suppliers of materials;
(vii) 受託製造廠以及其他 GMP 相關之委外活動供應者的認可及監督；	(vii) The approval and monitoring of contract manufacturers and providers of other GMP related outsourced activities;
(viii) 原物料及產品之儲存條件的指示與監測；	(viii) The designation and monitoring of storage conditions for materials and products;
(ix) 紀錄的保存；	(ix) The retention of records;
(x) 符合 GMP 要求之監督；	(x) The monitoring of compliance with the requirements of Good Manufacturing Practice;
(xi) 樣品的檢查、調查與抽取，以便監測可能會影響產品品質的因素；	(xi) The inspection, investigation, and taking of samples, in order to monitor factors which may affect product quality;
(xii) 參與製程性能、產品品質與製藥品質系統之管理審查，並倡導其持續的改進；	(xii) Participation in management reviews of process performance, product quality and of the Pharmaceutical Quality System and advocating continual improvement;
(xiii) 確保具備適時且有效的溝通及陳報流程，以將品質議題提升到適當管理階層的層級。	(xiii) Ensuring that a timely and effective communication and escalation process exists to raise quality issues to the appropriate levels of management.
訓練（TRAINING）	

2.10	藥廠對於因其職責會進入生產及儲存區域或管制實驗室的所有人員(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。	2.10	The manufacturer should provide training for all the personnel whose duties take them into production and storage 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.
2.11	除了有關製藥品質系統與優良製造規範的理論與實務基本訓練之外，新招募的人員應接受適合於其指定職責之適當訓練。同時也應提供持續的訓練，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核准的訓練計畫。訓練紀錄應予保存。	2.11	Besides the basic training on the theory and practice of the Pharmaceutical Quality System and 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.
2.12	對於在一有污染即產生危害之區域，例如在潔淨區域或在處理高活性、毒性、傳染性或致敏性物質之區域中工作的人員，應給予特別的訓練。	2.12	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.
2.13	對於參訪人員及未受過訓練的人員，盡量不要帶入生產區及品質管制區中。無法避免時，應予事先提供資訊並密切監督，特別是關於個人衛生及規定的防護裝。	2.13	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.

2.14 訓練期間，應充分討論製藥品質系統的概念及所有能增進其理解與執行的措施。	2.14 The Pharmaceutical Quality System and all the measures capable of improving its understanding and implementation should be fully discussed during the training sessions.
人員衛生（PERSONNEL HYGIENE）	
2.15 詳細的衛生計畫應予建立，並針對工廠內的不同需求調適。該計畫應包括人員健康、衛生習慣及服裝等相關程序。因其職責而進入生產區及管制區的每個人員，皆應了解這些程序並嚴格遵守。管理階層應推動衛生計畫並在訓練期間予以廣泛討論。	2.15 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.
2.16 所有人員於雇用時皆應接受體檢。藥廠應有職責建立指令，以確保人員與產品品質可能有關之健康狀況會為藥廠所悉。第一次體檢後，視工作與人員健康之需要，應再執行體檢。	2.16 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.
2.17 應盡可能採取步驟，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。	2.17 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.
2.18 進入製造區的每個人員皆應穿戴適合其所要執行操作之防護裝。	2.18 Every person entering the manufacturing areas should wear protective garments appropriate to the operations to be carried out.

2.19	生產區及儲存區應禁止飲食、嚼食或吸煙，或是儲存食物、飲料、菸類或個人的醫療用品。通常在製造區或產品可能會受到不良影響的任何其他區域中，應禁止任何不合衛生的行為。	2.19	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.
2.20	工作人員應避免雙手直接接觸暴露的產品及與產品接觸之設備的任何部分。	2.20	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.
2.21	應指導工作人員使用洗手設施。	2.21	Personnel should be instructed to use the hand-washing facilities.
2.22	其他任何特定的要求，例如製造無菌製劑等特殊類別的產品，收載於相關附則中。	2.22	Any specific requirements for the manufacture of special groups of products, for example sterile preparations, are covered in the annexes.
顧問（CONSULTANTS）			
2.23	顧問應有足夠的學識、訓練與經驗或其任何組合，以對其所被聘請之主題提供建議。	2.23	Consultants should have adequate education, training, and experience, or any combination thereof, to advise on the subject for which they are retained.
	顧問的姓名、地址、資格及提供之服務類型的紀錄，應加以保存。		Records should be maintained stating the name, address, qualifications, and type of service provided by these consultants.

第三章　廠房設施與設備（PREMISES AND EQUIPMENT）

原則（PRINCIPLE）			
	廠房設施及設備的定位、設計、建造、調適及維護皆應適合於其所要執行的作業。其配置與設計應將產生錯誤的風險降到最低並容許有效的清潔及維護保養，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。		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（PREMISES）			
	一般規定（General）		
3.1	當與保護產品製造的措施一併考量時，廠房設施應坐落於引起原物料或產品之最低污染風險環境中。	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.
3.2	廠房設施應謹慎維護，以確保其修理及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面程序消毒之。	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.
3.3	照明、溫度、濕度及通風均應適當，且不會對製造及儲存中的藥品或設備的正確功能有直接或間接之不利影響。	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.
3.4	廠房設施的設計與配置應提供最大的保護，以防止昆蟲或其他動物的入侵。	3.4	Premises should be designed and equipped so as to afford maximum protection against the entry of insects or other animals.

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應不得作為非該區工作人員的通路。	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.
	生產區（Production ***Area***）		
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（例如：青黴素類）或生物性製劑（例如：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，並執行必要的確效時，在例外的情形下，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及除草劑，不得於藥品之廠房設施中製造。	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.
3.7	廠房設施應配合作業順序及所要求的潔淨度等級予以配置，以容許在合乎邏輯順序的相連區域中生產。	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.

3.8	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，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，並使任何製造或管制步驟的遺漏或是誤用的風險降到最低。	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.
3.9	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)應平滑、無裂縫及無開口接縫，且不得脫落微粒物質，並應容易且有效地清潔，如有必要，還可消毒。	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.
3.10	管路工程、照明裝置、通氣口以及其他設施之設計與定位應避免產生難以清潔的凹處。為維護保養之目的，應盡量從製造區外進行。	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.
3.11	排水孔的大小應合適，並備有隔氣彎管的集水溝。應盡量避免開放式溝渠，必要時，應為淺溝，以利清潔與消毒。	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.

3.12	生產區應有效通風，並備有適合於所處理的產品、在該區域內從事的作業及外在環境等之空調設備（包含溫度，必要時包含濕度與過濾）。	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.
3.13	原料的秤重，通常應在專為該用途所設計之一間隔離的秤量室內為之。	3.13	Weighing of starting materials usually should be carried out in a separate weighing room designed for that use.
3.14	會產生粉塵的情況 (例如：抽樣、秤重、混合、製程操作及乾燥產品的分/包裝等期間中)，應採取特別的措施，以避免交叉污染並利於清潔。	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.
3.15	藥品分/包裝的廠房設施，應特別設計與配置，以避免混雜或交叉污染。	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.
3.16	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。	3.16	Productions areas should be well lit, particularly where visual on-line controls are carried out.
3.17	製程中管制不會對生產帶來任何風險者，可在生產區內執行。	3.17	In-process controls may be carried out within the production area provided they do not carry any risk for the production.
	儲存區（Storage ***Areas***）		
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有條理的儲存，包括：原料、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。	3.18	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.

3.19	儲存區應經設計或調適，以確保良好的儲存條件。特別是儲存區應保持潔淨與乾燥，並維持在可接受的溫度範圍內。有特別儲存條件要求時(例如溫度及濕度)，應提供這些儲存場所，並加以檢查/核對與監測。	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.
3.20	收貨區及出貨區應保護原物料及產品免於受天氣的影響。收貨區應加以設計並配置，以容許必要時能在儲存前清潔進廠原物料之容器。	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.
3.21	藉由儲存於分開的區域來確保隔離/待驗狀態者，該區域應標識清楚，其進入應限於經授權之人員。任何取代該實體隔離的系統，應提供同等的安全性。	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.
3.22	原料通常應有隔離的抽樣區域。在儲存區內執行抽樣者，應以可防止污染或交叉污染的方式執行之。	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.
3.23	對於拒用、回收或退回的原物料或產品應提供隔離的儲存區域。	3.23	Segregated areas should be provided for the storage of rejected, recalled or returned materials or products.
3.24	高活性物質或產品應儲存於安全且牢靠的區域中。	3.24	Highly active materials or products should be stored in safe and secure areas.
3.25	印刷的包裝材料對於藥品的符合性是很重要的，應特別注意這些包裝材料之安全及牢靠的儲存。	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.

	品質管制區（Quality Control Areas）		
3.26	通常，品質管制實驗室應與生產區隔離。這對生物學、微生物學及放射性同位素的管制實驗室特別重要。這些實驗室亦應互相隔離。	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.
3.27	管制實驗室應設計成適合於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。對於樣品與紀錄亦應有足夠且適當的儲存空間。	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.
3.28	為保護靈敏的儀器設備免於受振動、電子干擾及濕氣等之影響，分開的儀器室可能是必需的。	3.28	Separate rooms may be necessary to protect sensitive instruments from vibration, electrical interference, humidity, etc.
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。	3.29	Special requirements are needed in laboratories handling particular substances, such as biological or radioactive samples.
	附屬區域（Ancillary Areas）		
3.30	休息室與餐廳應與其他區域隔離。	3.30	Rest and refreshment rooms should be separate from other areas.
3.31	以更衣、盥洗及如廁為目的之設施應易於使用並適合使用之人數。廁所與生產區或儲存區不得直接相通。	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.
3.32	維修保養之工場應與生產區隔離並盡可能遠離。在生產區儲存零件及工具者，應儲存在其專用室或專用櫃中。	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.

3.33	動物室應與其他區域妥善隔離，並有分別的入口（動物的出入口）及空調處理設施。	3.33	Animal houses should be well isolated from other areas, with separate entrance (animal access) and air handling facilities.
設備（EQUIPMENT）			
3.34	製造設備應經設計、配置及維修保養，以符合其預定目的。	3.34	Manufacturing equipment should be designed, located and maintained to suit its intended purpose.
3.35	修理及維修保養作業不得對產品的品質呈現任何危害。	3.35	Repair and maintenance operations should not present any hazard to the quality of the products.
3.36	製造設備之設計，應使其能容易且徹底地清洗。該設備應依詳細的書面程序清洗，並僅以潔淨且乾燥的狀態儲存。	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.
3.37	洗滌及清潔設備應加以選擇與使用，使其不會成為污染的來源。	3.37	Washing and cleaning equipment should be chosen and used in order not to be a source 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。	3.38	Equipment should be installed in such a way as to prevent any risk of error or of contamination.
3.39	生產設備不得呈現對產品有任何危害。生產設備與產品接觸的部分，其反應性、加成性或吸附性不得高到足以影響產品的品質，而呈現任何危害。	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.
3.40	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。	3.40	Balances and measuring equipment of an appropriate range and precision should be available for production and control operations.

3.41	量測、秤重、記錄及管制之設備應在界定的時間間隔內，使用適當的方法校正並核對之。這些檢測的適當紀錄應予保存。	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.
3.42	固定的管線應清楚標示其內容物，可行時，流向亦應標示。	3.42	Fixed pipework should be clearly labelled to indicate the contents and, where applicable, the direction of flow.
3.43	蒸餾水、去離子水及合適時其他用水之配管應依書面程序執行滅菌處理。該文件應詳載微生物污染的行動限量及應採取的措施。	3.43	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.
3.44	有缺陷的設備，如果可能，應從生產區及品質管制區移出，或至少清楚標示其為有缺陷的設備。	3.44	Defective equipment should, if possible, be removed from production and quality control areas, or at least be clearly labeled as defective.

第四章　文件（DOCUMENTATION）

原則（PRINCIPLE）	
優良文件是構成品質保證系統必要的部分，而且是符合/遵循GMP要求之操作的關鍵。所使用之各種類型的文件與檔案資料，應在製造廠的品質管理系統中充分地界定。文件可能以多種形式存在，包括以紙本的、電子的或照像的資料。文件製作系統的主要目的，必須建立、管制、監控與記錄所有活動，該等活動會直接或間接影響藥物產品品質的所有層面。品質管理系統除提供各種流程以及任何觀察之評估的充分紀錄外，還應包含足夠的指導細節，以利共同理解這些要求，並使這些要求之持續應用得以證明。	Good documentation constitutes an essential part of the quality assurance system and is key to operating in compliance with GMP requirements. The various types of documents and media used should be fully defined in the manufacturer's Quality Management System. Documentation may exist in a variety of forms, including paper-based, electronic or photographic media. The main objective of the system of documentation utilized must be to establish, control, monitor and record all activities which directly or indirectly impact on all aspects of the quality of medicinal products. The Quality Management System should include sufficient instructional detail to facilitate a common understanding of the requirements, in addition to providing for sufficient recording of the various processes and evaluation of any observations, so that ongoing application of the requirements may be demonstrated.
用於管理與記錄GMP符合性之文件有兩種主要類型，包括指令（指導、要求）與紀錄/報告。應依適當的優良文件製作規範製作相關類型的文件。	There are two primary types of documentation used to manage and record GMP compliance: instructions (directions, requirements) and records/reports. Appropriate good documentation practice should be applied with respect to the type of document.

應實施適當的管制，以確保文件的正確性、完整性、可得性與可讀性。指導文件應無錯誤並且可以以書面取得。「書面」意指在檔案資料上所記錄或文件化的數據，藉以成為可讀取的形式。	Suitable controls should be implemented to ensure the accuracy, integrity, availability and legibility of documents. Instruction documents should be free from errors and available in writing. The term 'written' means recorded, or documented on media from which data may be rendered in a human readable form.
所需要的 GMP 文件（按類型） 【REQUIRED GMP DOCUMENTATION (BY TYPE)】	
工廠基本資料（Site Master File）：描述製造廠之GMP相關活動的文件。	**Site Master File:** A document describing the GMP related activities of the manufacturer.
指令（指導或要求）類型【Instructions (directions, or requirements) type】：	
規格：詳細描述在製造期間所使用的或所取得的原物料或產品必須符合的要求。規格是作為品質評估的基礎。	**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.
製造配方、操作/加工、分/包裝與檢驗的指令： 提供所要使用之所有原料、設備與電腦化系統（如有）的細節，並且規定所有操作/加工、分/包裝、取樣與檢驗的指導。所要使用的製程中管制與製程分析技術，連同允收標準（合適時），應該加以規定。	**Manufacturing Formulae, Processing, Packaging and Testing Instructions:** Provide detail all the starting materials, equipment and computerised systems (if any) to be used and specify all processing, packaging, sampling and testing instructions. In-process controls and process analytical technologies to be employed should be specified where relevant, together with acceptance criteria.
程序：（或稱為標準作業程序，簡稱SOPs），對於執行某些操作/作業給予指導。	**Procedures:** (Otherwise known as Standard Operating Procedures, or SOPs), give directions for performing certain operations.
計畫書：對於執行與記錄某些需謹慎操作/作業給予指令。	**Protocols:** Give instructions for performing and recording certain discreet operations.

技術協議：委託者與受託者之間對於委外活動的協議。	**Technical Agreements:** Are agreed between contract givers and acceptors for outsourced activities.
紀錄/報告類型（Record/Report type）：	
紀錄：提供所採取之各種行動的證據，以證明遵循指令，例如：活動、事件、調查及在製造批次的情況下，每一個產品批次的歷史，包含其運銷在內。紀錄包括使用於產生其他紀錄的原始數據。對於電子紀錄，受管制的使用者應界定哪些數據要當作原始數據使用。至少，應將所有據以決定品質的數據，界定為原始數據。	**Records:** Provide evidence of various actions taken to demonstrate compliance with instructions, e.g. activities, events, investigations, and in the case of manufactured batches a history of each batch of product, including its distribution. Records include the raw data which is used to generate other records. For electronic records regulated users should define which data are to be used as raw data. At least, all data on which quality decisions are based should be defined as raw data.
分析證明書：提供關於產品或原物料樣品之檢驗結果的摘要[1]，連同對所陳述之規格符合性的評估。	**Certificates of Analysis:** Provide a summary of testing results on samples of products or materials[1] together with the evaluation for compliance to a stated specification.
報告：將特定的運用、計畫或調查的執行/處理，連同結果、結論與建議加以文件化。	**Reports:** Document the conduct of particular exercises, projects or investigations, together with results, conclusions and recommendations.
文件的產生與管制（GENERATION AND CONTROL OF DOCUMENTATION）	

4.1	應界定所有文件的類型並遵守之。此等要求同樣適用於文件檔案資料類型的所有形式。複雜性系統需經理解、完善文件化、確效，並具備適當的管制。許多文件（指令及/或記錄）可能以混合形式存在，亦即，有些要件是以電子化為基礎，其它則以紙本為基礎。對於混合系統與同質系統兩者，其正本、法定副本、數據處理與紀錄之關係與管制措施需加以陳述。對於電子文件，例如樣本、表單與主文件應執行適當管制。應具備適當的管制以確保在整個保存期間該記錄的完整性。	4.1	All types of document should be defined and adhered to. The requirements apply equally to all forms of document media types. Complex systems need to be understood, well documented, validated, and adequate controls should be in place. Many documents (instructions and/or records) may exist in hybrid forms, i.e. some elements as electronic and others as paper based. Relationships and control measures for master documents, official copies, data handling and records need to be stated for both hybrid and homogenous systems. Appropriate controls for electronic documents such as templates, forms, and master documents should be implemented. Appropriate controls should be in place to ensure the integrity of the record throughout the retention period.
4.2	文件應經謹慎設計、製作、審核及分發。合適時，該等文件應符合產品規格檔案、製造與上市許可文件的相關部分。來自正本之工作文件的複製，不得因複製過程導入任何錯誤。	4.2	Documents should be designed, prepared, reviewed, and distributed with care. They should comply with the relevant parts of Product Specification Files, Manufacturing and Marketing Authorisation dossiers, as appropriate. The reproduction of working documents from master documents should not allow any error to be introduced through the reproduction process.
4.3	含指令的文件應由適當且經授權的人員核定、簽章並註明日期。文件應具有明確之內容且應為獨特可確認的。生效日期應加以界定。	4.3	Documents containing instructions should be approved, signed and dated by appropriate and authorised persons. Documents should have unambiguous contents and be uniquely identifiable. The effective date should be defined.

4.4	含指令的文件，應以有條理的方式編排且易於核對。文件之格式與語文應配合其預定的用途。標準作業程序、作業指令與方法皆應以強制性的格式書寫。	4.4	Documents containing instructions should be laid out in an orderly fashion and be easy to check. The style and language of documents should fit with their intended use. Standard Operating Procedures, Work Instructions and Methods should be written in an imperative mandatory style.
4.5	品質管理系統內的文件應定期檢討且應保持其最新版本。當一份文件經修訂後，應有一系統運作，以防止作廢文件被誤用。	4.5	Documents within the Quality Management System 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.
4.6	文件本身不得用手寫，但需手寫填入數據時，應有足夠的空間供此類數據的填入。	4.6	Documents should not be hand-written; although, where documents require the entry of data, sufficient space should be provided for such entries.
優良文件製作規範（GOOD DOCUMENTATION PRACTICES）			
4.7	手寫填入資料時，應以清晰、可讀且擦不掉的方式為之。	4.7	Handwritten entries should be made in clear, legible, indelible way.
4.8	採取每項行動時，即應記錄。因此，與藥品製造有關的所有重要活動皆可追溯。	4.8	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.
4.9	文件上對於填入項目所做的任何更改應予簽章並註明日期；該更改應允許讀取原來的資訊。合適時，更改理由應記錄之。	4.9	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.
文件保存（RETENTION OF DOCUMENTS）			

4.10	應清楚界定與每個製造活動相關的紀錄及其存放處。必須具備安全管制，以確保在整個保存期間紀錄的完整性，且合適時必須進行確效。	4.10	It should be clearly defined which record is related to each manufacturing activity and where this record is located. Secure controls must be in place to ensure the integrity of the record throughout the retention period and validated where appropriate.
4.11	對於批次文件，特定的要求適用於必須保存到該批次之末效日期後一年，或保存到在該批次經由被授權人認定後至少五年，兩者取其較長者。對於研究用藥品，批次文件必須保存到所使用之該批次的最終臨床試驗完成後或試驗正式中止後至少五年。對於文件之保存的其它要求，可能敘述於特定類型產品（例如，新興治療藥品）之相關法規中，並規定某些文件應採用較長的保存期限。	4.11	Specific requirements apply to batch documentation which must be kept for one year after expiry of the batch to which it relates or at least five years after certification of the batch by the Authorised Person, whichever is the longer. For investigational medicinal products, the batch documentation must be kept for at least five years after the completion or formal discontinuation of the last clinical trial in which the batch was used. Other requirements for retention of documentation may be described in legislation in relation to specific types of product (e.g. Advanced Therapy Medicinal Products) and specify that longer retention periods be applied to certain documents.

4.12	對於其他類型的文件，保存期限將依其作業活動而定。上市許可資訊的關鍵文件，包含原始數據（例如：與確效或安定性相關者）在內，應在該上市許可仍然有效的期間加以保存。當數據已由一套完整的新數據取代時，將某些文件（例如，支持確效報告或安定性報告的原始數據）廢除，視為可接受的。對此文件廢除的正當性證明應加以文件化，且應考慮批次文件保存的要求；例如，在製程確效數據的情況中，其所伴隨的原始數據應予保存，其期限應至少與基於該確效作業所支持放行的所有批次紀錄的期間相同。	4.12	For other types of documentation, the retention period will depend on the business activity which the documentation supports. Critical documentation, including raw data (for example relating to validation or stability), which supports information in the Marketing Authorisation should be retained whilst the authorization remains in force. It may be considered acceptable to retire certain documentation (e.g. raw data supporting validation reports or stability reports) where the data has been superseded by a full set of new data. Justification for this should be documented and should take into account the requirements for retention of batch documentation; for example, in the case of process validation data, the accompanying raw data should be retained for a period at least as long as the records for all batches whose release has been supported on the basis of that validation exercise.
	下節提供所需文件的一些實例。為確保產品品質與病患安全，品質管理系統應敘明所需要的所有文件。		The following section gives some examples of required documents. The quality management system should describe all documents required to ensure product quality and patient safety.
規格（SPECIFICATIONS）			
4.13	原料、包裝材料及最終產品，應有適當經核准且註明日期的規格。	4.13	There should be appropriately authorised and dated specifications for starting and packaging materials, and finished products.
原料及包裝材料的規格（Specifications for starting and packaging materials）			

4.14 原料及直接包裝或印刷包裝材料之規格，如果可行，應包括下列項目:	4.14 Specifications for starting and primary or printed packaging materials should include or provide reference to, if applicable:
a) 原物料的描述，包括：	a) A description of the materials, including:
– 指定的名稱及內部的參考代碼；	– The designated name and the internal code reference;
– 藥典個論的參考資料(如有時)；	– The reference, if any, to a pharmacopoeial monograph;
– 認可的供應商，及其原始的生產者（如可能時)；	– The approved suppliers and, if reasonable, the original producer of the material;
– 印刷材料的樣本；	– A specimen of printed materials;
b) 抽樣、檢驗的指示；	b) Directions for sampling and testing;
c) 具有合格標準範圍之定性及定量的要求；	c) Qualitative and quantitative requirements with acceptance limits;
d) 儲存的條件及注意事項；	d) Storage conditions and precautions;
e) 再驗前的最長儲存期間。	e) The maximum period of storage before re-examination.
半製品/中間產品及待分/包裝產品的規格 （Specifications for intermediate and bulk products）	
4.15 對於關鍵步驟的、採購或發送之半製品/中間產品與待分/包裝產品應具有規格。合適時,這些規格應類似於原料或最終產品的規格。	4.15 Specifications for intermediate and bulk products should be available for critical steps or if these are purchased or dispatched. The specifications should be similar to specifications for starting materials or for finished products, as appropriate.
最終產品的規格（Specifications for finished products）	
4.16 最終產品規格應包括或提供下列項目：	4.16 Specifications for finished products should include or provide reference to:
a) 產品之指定名稱及其參考代碼（可行時)；	a) The designated name of the product and the code reference where applicable;
b) 配方	b) The formula;

c) 產品劑型及包裝細節的描述；	c) A description of the pharmaceutical form and package details;
d) 抽樣及檢驗的指示；	d) Directions for sampling and testing;
e) 具有合格標準範圍之定性及定量的要求；	e) The qualitative and quantitative requirements, with the acceptance limits;
f) 儲存條件及任何特別處理的注意事項（可行時）;	f) The storage conditions and any special handling precautions, where applicable;
g) 架儲期。	g) The shelf-life.
製造配方及操作指令 **（MANUFACTURING FORMULA AND PROCESSING INSTRUCTIONS）**	
對於所要製造的每一個產品與批量應有經核准的書面製造配方與操作指令。	Approved, written Manufacturing Formula and Processing Instructions should exist for each product and batch size to be manufactured.
4.17 製造配方應包括下列項目:	4.17 The Manufacturing Formula should include:
a) 產品名稱及其規格有關的產品參考代碼；	a) The name of the product, with a product reference code relating to its specification;
b) 產品劑型、含量及批量的描述；	b) A description of the pharmaceutical form, strength of the product and batch size;
c) 所有使用之原料及其用量的清單，並應敘明在操作過程中可能喪失之任何物質；	c) A list of all starting materials to be used, with the amount of each, described; mention should be made of any substance that may disappear in the course of processing;
d) 說明預期最終產率及其允收範圍，以及相關半製品/中間產品產率（可行時）。	d) A statement of the expected final yield with the acceptable limits, and of relevant intermediate yields, where applicable.
4.18 操作指令應包括下列項目：	4.18 The Processing Instructions should include:

a) 作業場所及主要設備的說明；	a) A statement of the processing location and the principal equipment to be used;
b) 準備關鍵設備所要使用的方法（例如清潔、組裝、校正、滅菌）或該等方法的參考資料；	b) The methods, or reference to the methods, to be used for preparing the critical equipment (e.g. cleaning, assembling, calibrating, sterilising);
c) 檢查其設備與工作場所無先前的產品、亦無非本製程所需的文件或原物料，且該設備是潔淨並適合使用；	c) 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;
d) 詳細的逐步操作指令【例如，原物料的檢查/核對、前處理、添加原物料的順序、關鍵製程參數（時間、溫度等）】；	d) Detailed stepwise processing instructions [e.g. checks on materials, pre-treatments, sequence for adding materials, critical process parameters (time, temp etc)];
e) 任何製程中管制的指令及其範圍；	e) The instructions for any in-process controls with their limits;
f) 必要時，待分/包裝產品之儲存要求；可行時，包括其容器、標示及特別的儲存條件；	f) Where necessary, the requirements for bulk storage of the products; including the container, labeling and special storage conditions where applicable;
g) 應遵守的任何特別注意事項。	g) Any special precautions to be observed.
分/包裝指令（Packaging Instructions）	
4.19 每項產品的包裝量與形式應有經核准的分/包裝指令。這些指令通常應包括下列項目或其參考資料：	4.19 Approved Packaging Instructions for each product, pack size and type should exist. These should include, or have a reference to, the following:
a) 產品名稱；包括待分/包裝產品與最終產品的批號；	a) Name of the product; including the batch number of bulk and finished product;

b) 劑型，及其含量（可行時）的描述；	b) Description of its pharmaceutical form, and strength where applicable;
c) 包裝量，以產品在最終容器的數量、重量或容量表示；	c) The pack size expressed in terms of the number, weight or volume of the product in the final container;
d) 所需全部包裝材料的清單，包括其數量、尺寸與型式及每種包裝材料之規格有關的代碼或參考號碼；	d) A complete list of all the packaging materials required, including quantities, sizes and types, with the code or reference number relating to the specifications of each packaging material;
e) 合適時，相關已印刷之包裝材料的實例或複製品，以及產品批號及架儲期打印位置之樣本；	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;
f) 檢查其設備與工作場所站無先前的產品、亦無非本包裝作業所需的文件或原物料（清線），且該設備是潔淨並適合使用；	f) Checks that the equipment and work station are clear of previous products, documents or materials not required for the planned packaging operations (line clearance), and that equipment is clean and suitable for use;
g) 應遵行的特別注意事項，包括謹慎檢查作業區與設備，以確認作業開始前已完成分/包裝線的清線工作；	g) Special precautions to be observed, including a careful examination of the area and equipment in order to ascertain the line clearance before operations begin;
h) 分/包裝作業之描述，包括任何重要的輔助作業及所需使用的設備；	h) A description of the packaging operation, including any significant subsidiary operations, and equipment to be used;

i) 製程中管制的細節，並有抽樣指令及允收範圍。	i) Details of in-process controls with instructions for sampling and acceptance limits.
批次製造紀錄（Batch Processing Record）	
4.20 每一製造的批次應保存其批次製造紀錄，且依據現行認可的製造配方及操作指令。並且應該包含下列資訊：	4.20 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, and should contain the following information:
a) 產品名稱與批號；	a) The name and batch number of the product;
b) 生產之開始、重要中間階段及完成的日期與時間；	b) Dates and times of commencement, of significant intermediate stages and of completion of production;
c) 執行每一重要製程步驟之作業人員的簽名，以及合適時，這些作業應有核對者的簽名；	c) Identification (initials) of the operator(s) who performed each significant step of the process and, where appropriate, the name of any person who checked these operations;
d) 每一原料的批號及/或分析管制的號碼以及實際秤取之重量（包括所添加之任何收回或重處理的半製品之批號及重量）；	d) 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) 任何相關之操作作業或事件及使用之主要設備；	e) Any relevant processing operation or event and major equipment used;
f) 製程中管制的紀錄、執行該管制人員的簽名及結果；	f) A record of the in-process controls and the initials of the person(s) carrying them out, and the results obtained;

g) 製造的不同階段及相關階段所獲得產品之產率；	g) The product yield obtained at different and pertinent stages of manufacture;
h) 特別問題之備註，包含來自製造配方及操作指令之任何偏差的詳細記錄，並有經簽章認可；	h) Notes on special problems including details, with signed authorisation for any deviation from the Manufacturing Formula and Processing Instructions;
i) 經由該製程操作的負責人員核准。	i) Approval by the person responsible for the processing operations.
註：經確效的製程如為持續監測與管制時，則自動產生的報告可能侷限於符合性摘要與異常/偏離規格（OOS）數據報告。	**Note:** Where a validated process is continuously monitored and controlled, then automatically generated reports may be limited to compliance summaries and exception/ out-ofspecification (OOS) data reports.
批次分/包裝紀錄（Batch Packaging Record）	
4.21 每一操作批次或部分批次應保存其批次分/包裝紀錄，該記錄應依據分/包裝指令的相關部分。	4.21 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.
批次分/包裝紀錄應包含下列資訊：	The batch packaging record should contain the following information:
a) 產品名稱與批號；	a) The name and batch number of the product;
b) 分/包裝作業的日期及時間；	b) The date(s) and times of the packaging operations;
c) 執行每一重要分/包裝步驟之作業人員的簽名，以及合適時，這些作業應有核對者的簽名；	c) Identification (initials) of the operator(s) who performed each significant step of the process and, where appropriate, the name of any person who checked these operations;
d) 分/包裝指令之識別與符合性的核對紀錄，至少包含製程中管制的結果；	d) Records of checks for identity and conformity with the packaging instructions, including the results of in-process controls;

e) 執行分/包裝作業的細節，包含使用的設備與分/包裝線的參考資料；	e) Details of the packaging operations carried out, including references to equipment and the packaging lines used;
f) 每當可能時，使用之印刷包裝材料的樣品，包括批次代碼、末效日期及任何附加套印的樣本；	f) Whenever possible, samples of printed packaging materials used, including specimens of the batch coding, expiry dating and any additional overprinting;
g) 特別問題或異常事件之備註，包含來自分/包裝指令之任何偏差的詳細記錄，並有經簽章認可；	g) Notes on any special problems or unusual events including details, with signed authorisation for any deviation from the Packaging Instructions;
h) 所有發出、使用、銷毀或退回庫存之印刷的包裝材料與待分/包裝產品的數量、參考號碼或其識別，及所得之產品數量，以提供適當的數量調和。在分/包裝期間備有穩固的電子管制時，不包含這個資訊可能具有其正當性；	h) 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. Where there are robust electronic controls in place during packaging there may be justification for not including this information;
i) 經由該分/包裝作業的負責人員核准。	i) Approval by the person responsible for the packaging operations.
程序與紀錄（PROCEDURES AND RECORDS）	
接收（Receipt）	
4.22 每一原料（包括待分/包裝產品、半製品/中間產品或最終產品）、直接包裝材料、間接包裝材料及印刷包裝材料於每次交貨時的接收，皆應有書面程序與紀錄。	4.22 There should be written procedures and records for the receipt of each delivery of each starting material, (including bulk, intermediate or finished goods), primary, secondary and printed packaging materials.
4.23 接收紀錄應包括：	4.23 The records of the receipts should include:

a) 送貨單及容器上原物料之名稱；	a) The name of the material on the delivery note and the containers;
b) 原物料之「廠內」的名稱及/或代碼（如異於a時）；	b) The "in-house" name and/or code of material (if different from a);
c) 接收日期；	c) Date of receipt;
d) 供應商的名稱及製造廠的名稱；	d) Supplier’s name and, manufacturer’s name;
e) 製造廠的批號或參考號碼；	e) Manufacturer’s batch or reference number;
f) 接收的總量及容器的數目；	f) Total quantity and number of containers received;
g) 接收後指定的批號；	g) The batch number assigned after receipt;
h) 任何相關的加註。	h) Any relevant comment.
4.24 應有原料、包裝材料及合適時其他材料的廠內標示、隔離/待驗及儲存的書面程序。	4.24 There should be written procedures for the internal labeling, quarantine and storage of starting materials, packaging materials and other materials, as appropriate.
抽樣（Sampling）	
4.25 抽樣應有書面程序。該程序應包括所要使用的方法與設備、抽樣量及應遵守的預防措施，以避免原物料的污染或其品質的降低。	4.25 There should be written procedures for sampling, which include 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.
檢驗（Testing）	
4.26 在不同製造階段檢驗原物料及產品，應有書面的程序。該程序描述使用的方法及設備。執行的檢驗應加以記錄。	4.26 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.
其他（Other）	

4.27	原物料及產品之放行與拒用，特別是由指派之被授權人員對最終產品放行供銷售，應有書面程序。所有紀錄應可供被授權人取得。應備有系統，以顯示特別的觀察所見，以及對於關鍵數據之任何變更。	4.27	Written release and rejection procedures should be available for materials and products, and in particular for the certification for sale of the finished product by the Authorised Person(s). All records should be available to the Authorised Person. A system should be in place to indicate special observations and any changes to critical data.
4.28	應保存每一產品之運銷紀錄，以利必要時該批次的回收。	4.28	Records should be maintained for the distribution of each batch of a product in order to facilitate recall of any batch, if necessary.
4.29	對下列事項應有書面的政策、程序、計畫書、報告及所採取行動或已達成結論的相關紀錄，合適時，包含下列實例：	4.29	There should be written policies, procedures, protocols, reports and the associated records of actions taken or conclusions reached, where appropriate, for the following examples:
	– 製程、設備與系統的確效與驗證；		– Validation and qualification of processes, equipment and systems;
	– 設備之組裝及校正；		– Equipment assembly and calibration;
	– 技術移轉；		– Technology transfer;
	– 維護保養、清潔與滅菌處理；		– Maintenance, cleaning and sanitation;
	– 人事，包含人員簽名清單、在GMP與技術事務、衣著與衛生上的訓練以及確認訓練的有效性；		– Personnel matters including signature lists, training in GMP and technical matters, clothing and hygiene and verification of the effectiveness of training.
	– 環境監測；		– Environmental monitoring;
	– 防蟲鼠；		– Pest control;
	– 申訴；		– Complaints;
	– 回收；		– Recalls;
	– 退回；		– Returns;
	– 變更管制；		– Change control;
	– 偏差與不符合的調查；		– Investigations into deviations and non-conformances;
	– 內部品質/GMP符合性稽查；		– Internal quality/GMP compliance audits;

– 紀錄的摘要（合適時）（例如，產品品質檢討）；	– Summaries of records where appropriate (e.g. product quality review);
– 供應商稽查。	– Supplier audits.
4.30 主要的製造與檢驗設備應有清楚的操作程序。	4.30 Clear operating procedures should be available for major items of manufacturing and test equipment.
4.31 應保存主要或關鍵的分析檢驗、生產設備及產品生產區域的日誌。合適時，該日誌應依時序記錄任何使用的區域、設備/方法、校正、維護保養及清潔或維修作業，包含執行這些操作的日期與人員的簽名。	4.31 Logbooks should be kept for major or critical analytical testing, production equipment, and areas where product has been processed. They should be used to record in chronological order, as appropriate, any use of the area, equipment/method, calibrations, maintenance, cleaning or repair operations, including the dates and identity of people who carried these operations out.
4.32 品質管理系統內的文件清單應加以維護。	4.32 An inventory of documents within the Quality Management System should be maintained.
[1] 或者，本證明書可以全部或部分根據來自依照所核准之上市許可檔案文件的批次相關製程分析技術（PAT）、參數或計量學之即時數據（摘要與異常報告）的評估。	[1] Alternatively the certification may be based, in-whole or in-part, on the assessment of real time data (summaries and exception reports) from batch related process analytical technology (PAT), parameters or metrics as per the approved marketing authorisation dossier.

第五章　生產（PRODUCTION）

原則（PRINCIPLE）			
	生產作業應遵循清楚界定的程序，且符合優良製造規範的原則，以獲得要求之品質的產品，並應符合相關的製造及上市許可。		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.
一般規定（GENERAL）			
5.1	生產應由能勝任者執行與監督。	5.1	Production should be performed and supervised by competent people.
5.2	原物料與產品的所有處理，例如接收、待驗、抽樣、儲存、標示、調配、製造、分/包裝及運銷，應依書面程序或指令執行，必要時應予記錄。	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.
5.3	所有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。	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.
5.4	容器之破損及對原物料品質可能產生其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。	5.4	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.
5.5	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，直到其經放行供使用或運銷為止。	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.

5.6	採購的半製品/中間產品或待分/包裝產品，在接收時應視同原料處理。	5.6	Intermediate and bulk products purchased as such should be handled on receipt as though they were starting materials.
5.7	所有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，以容許批次的區隔及庫存品的輪換。	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.
5.8	視需要，應核對產率及進行重量/數量調和，以確保無超出允收範圍的差異。	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.
5.9	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，除非無混雜或交叉污染的風險。	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.
5.10	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。	5.10	At every stage of processing, products and materials should be protected from microbial and other contamination.
5.11	處理乾燥的原物料及產品時，應採取特別的防範措施，以防止粉塵的產生及散佈。特別適用於高活性或高致敏性物質的處理。	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.
5.12	操作全程中，所有原物料、半製品容器、設備的主要項目及合適時使用的操作室皆應標示，否則，應以操作中產品或原物料、其含量（如果可行）及批號等標示予以識別。可行時，該標示亦應提及生產階段。	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.

5.13	用於容器、設備或作業場所的標示卡應清楚、明確，且使用公司一致的格式。標籤上除文字外，使用顏色標示其狀態(例如：待驗、合格、拒用、清潔…等)，通常是有幫助的。	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, ...).
5.14	為確保用於將產品從一個區域輸送到另外一個區域的管線及其他設備係以正確的方式連接，應執行檢查。	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.
5.15	應盡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。	5.15	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.
5.16	進入生產廠房應限於被授權人員。	5.16	Access to production premises should be restricted to authorised personnel.
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。	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.
生產中交叉污染的防止 （PREVENTION OF CROSS-CONTAMINATION IN PRODUCTION）			

5.18 應防止原料或產品被另一原物料或產品污染。該意外交叉污染的風險，源於製程中未管制之原物料及產品所產生的粉塵、氣體、蒸氣、噴霧或微生物、設備上的殘留物及因作業人員的服裝等。該風險的嚴重性隨污染物的種類及被污染的產品而異，其中最具危害的污染物是高致敏性物質、含有活體的生物製劑、某些荷爾蒙類、細胞毒類及其他高活性的物質。污染尤對以注射、大劑量及/或長期投用的產品之使用最具風險。	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.
5.19 交叉污染應以適當的技術或有組織的措施避免之，例如：	5.19 Cross-contamination should be avoided by appropriate technical or organisational measures, for example:
a) 在隔離的區域(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)，或採分隔時段切換生產，其後應緊接著適當的清潔處理；	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;
b) 備有適當的氣鎖室及空氣抽除設備；	b) providing appropriate air-locks and air extraction;
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；	c) minimising the risk of contamination caused by recirculation or re-entry of untreated or insufficiently treated air;

d) 製造具交叉污染特別風險之產品的區域內應保持穿著防護裝；	d) keeping protective clothing inside areas where products with special risk of cross-contamination are processed;
e) 設備的無效清潔是交叉污染的普遍來源，故應使用已知有效的清潔及去污染程序；	e) using cleaning and decontamination procedures of known effectiveness, as ineffective cleaning of equipment is a common source of cross contamination;
f) 使用密閉的生產系統；	f) using "closed systems" of production;
g) 檢驗設備上的殘留物並使用清潔狀態標籤。	g) testing for residues and use of cleaning status labels on equipment.
5.20 應依規定程序定期檢查防止交叉污染的措施及其有效性。	5.20 Measures to prevent cross-contamination and their effectiveness should be checked periodically according to set procedures.
確效（Validation ）	
5.21 確效試驗應強化優良製造規範，並依所界定的程序實施。其結果及結論應予記錄。	5.21 Validation studies should reinforce Good Manufacturing Practice and be conducted in accordance with defined procedures. Results and conclusions should be recorded.
5.22 當採用任何新的製造配方或製備方法時，應採取步驟以證明其對例行操作的適用性。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出與所要求品質一致之產品。	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.

5.23	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。	5.23	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.
5.24	製程及程序應執行定期關鍵性再確效，以確保其維持達成預定結果的能力。	5.24	Processes and procedures should undergo periodic critical revalidation to ensure that they remain capable of achieving the intended results.
原料（STARTING MATERIALS）			
5.25	原料的採購是一項重要的作業，應有對供應商具特別且充分瞭解的人員參與。	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.
5.26	原料僅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。建議藥廠建立原料規格時應與供應商討論。涉及原料之生產與管制的所有層面，包括其處理、標示、分/包裝的要求，以及申訴和拒用的程序等，與製造廠及供應商討論是有助益的。	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.
5.27	每一次交貨，應檢查/核對容器的包裝、封條的完整性及送貨單與供應商標示之一致性。	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.
5.28	原物料之一次交貨是由不同批次所組成者，每一批次應各自考慮其抽樣、檢驗與放行。	5.28	If one material delivery is made up of different batches, each batch must be considered as separate for sampling, testing and release.

5.29	儲存區的原料應適當地標示 (請參見第五章，第十三條)。標籤上應至少記載下列資料：	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:
	➢ 產品的指定名稱及其內部參考代碼(可行時)；		➢ the designated name of the product and the internal code reference where applicable;
	➢ 接收時所給予的批號；		➢ a batch number given at receipt;
	➢ 合適時，內容物的狀態(例如：待驗中、檢驗中、放行、拒用)；		➢ where appropriate, the status of the contents (e.g. in quarantine, on test, released, rejected);
	➢ 合適時，末效日期或再檢驗的日期。		➢ where appropriate, an expiry date or a date beyond which retesting is necessary.
	採用完全電腦化之儲存系統者，上述所有資料不必以易讀的方式印在標籤上。		When fully computerised storage systems are used, all the above information should not necessarily be in a legible form on the label.
5.30	應有適當的程序或措施來確保每一個原料容器之內容物的同一性。已抽樣之原包裝容器應予識別與標示 (請參見第六章，第十三條)。	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).
5.31	僅有經品質管制部門放行，且還在架儲期間內的原料始可使用。	5.31	Only starting materials which have been released by the Quality Control Department and which are within their shelf-life should be used.
5.32	原料只得由指定的人員依書面程序調配，以確保將正確的原料準確地稱入或量入潔淨且適切標示的容器中。	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.
5.33	每一經調配之原料及其重量或容量，皆應個別檢查/核對並予以記錄。	5.33	Each dispensed material and its weight or volume should be independently checked and the check recorded.

5.34 每一批次調配的原料應保存在一起，並明顯地標示。	5.34 Materials dispensed for each batch should be kept together and conspicuously labelled as such.
半製品/中間產品及待分/包裝產品的操作作業（PROCESSING OPERATIONS INTERMEDIATE AND BULK PRODUCTS）	
5.35 任何操作作業開始前，應採取步驟，以確保作業區及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。	5.35 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.
5.36 半製品/中間產品或待分/包裝產品應保存在適當的條件下。	5.36 Intermediate and bulk products should be kept under appropriate conditions.
5.37 關鍵製程應經確效(參見本章之「確效」)。	5.37 Critical processes should be validated (see "VALIDATION" in this Chapter).
5.38 任何必要的製程中管制及環境管制均應執行並予記錄。	5.38 Any necessary in-process controls and environmental controls should be carried out and recorded.
5.39 與預期產率的任何顯著偏差均應予記錄並加以調查。	5.39 Any significant deviation from the expected yield should be recorded and investigated.
包裝材料（PACKAGING MATERIALS）	
5.40 直接包裝材料及經印刷的包裝材料之採購、處理及管制應比照原料給予同等注意。	5.40 The purchase, handling and control of primary and printed packaging materials should be accorded attention similar to that given to starting materials.
5.41 經印刷的包裝材料應予特別注意。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。切式標籤及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人員，依認可且文件化的程序發放使用。	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.

5.42	每一次交貨或每一批次之經印刷的包裝材料或直接包裝材料，均應給予專有的參考號碼或辨識標記。	5.42	Each delivery or batch of printed or primary packaging material should be given a specific reference number or identification mark.
5.43	過期或作廢的直接包裝材料或經印刷的包裝材料應予銷毀，並將該處置加以記錄。	5.43	Outdated or obsolete primary packaging material or printed packaging material should be destroyed and this disposal recorded.
分/包裝作業（PACKAGING OPERATIONS）			
5.44	建立分/包裝作業計畫時應特別注意，將交叉污染、混雜或替代的風險降到最低。除有實體隔離外，不同的產品不得在緊密相鄰處分/包裝。	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.
5.45	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。	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.
5.46	作業中的產品名稱及批號，應標明在每一個分/包裝站或線上。	5.46	The name and batch number of the product being handled should be displayed at each packaging station or line.
5.47	所有產品及待用的包裝材料，交給分/包裝部門時皆應與分/包裝指令檢查/核對其數量、同一性及一致性。	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.

5.48	充填用的容器在充填前應為潔淨的。應注意避免任何污染物並予以移除，例如玻璃碎片及金屬粒子。	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.
5.49	通常，充填與密封後應盡快加以標示。若非如此，則應採取適當的程序，以確保不會發生混雜或貼錯標籤。	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.
5.50	任何印刷作業（例如代碼、末效日期）的正確性，不管是個別進行或是在分/包裝作業的過程中進行，應予以檢查/核對並加以記錄。手工印刷應予注意，並定時再檢查/核對。	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.
5.51	當使用切式標籤和執行離線套印時，應予特別注意。在幫助避免混雜方面，捲筒式標籤通常優於切式標籤。	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.
5.52	為確保電子讀碼機、標籤計數器或其他類似的裝置係正確操作，應執行檢查/核對。	5.52	Checks should be made to ensure that any electronic code readers, label counters or similar devices are operating correctly.
5.53	經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。	5.53	Printed and embossed information on packaging materials should be distinct and resistant to fading or erasing.
5.54	於分/包裝期間，產品的線上管制應進行檢查/核對，至少包括下列項目：	5.54	On-line control of the product during packaging should include at least checking the following:
	a) 包裝的一般外觀；		a) general appearance of the packages;
	b) 包裝是否完整；		b) whether the packages are complete;

	c) 是否使用正確的產品與包裝材料;		c) whether the correct products and packaging materials are used;
	d) 任何套印是否正確；		d) whether any over-printing is correct;
	e) 分/包裝線上監視器的正確運轉。		e) correct functioning of line monitors.
	從分/包裝線上取出的樣品不得置回。		Samples taken away from the packaging line should not be returned.
5.55	已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。	5.55	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.
5.56	在待分/包裝產品與印刷之包裝材料的數量及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於放行前進行調查並予以滿意地說明。	5.56	Any significant or unusual discrepancy observed during reconciliation of the amount of bulk product and printed packaging materials and the number of units produced should be investigated and satisfactorily accounted for before release.
5.57	分/包裝作業一經完成後，任何未使用而印有批號之印刷包裝材料應予銷毀，並將該銷毀加以記錄。未印批號之印刷包裝材料要退回庫存者，應遵循書面程序。	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.
最終產品（FINISHED PRODUCTS）			
5.58	最終產品應依藥廠既訂條件下保存於隔離待驗區，直到最終放行為止。	5.58	Finished products should be held in quarantine until their final release under conditions established by the manufacturer.
5.59	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)。	5.59	The evaluation of finished products and documentation which is necessary before release of product for sale are described in Chapter 6 (Quality Control).

5.60	放行後，最終產品應依藥廠既訂條件作為可用庫存品儲存。	5.60	After release, finished products should be stored as usable stock under conditions established by the manufacturer.
拒用的、收回的以及退回的原物料（REJECTED, RECOVERED AND RETURNED MATERIALS）			
5.61	拒用的原物料及產品應清楚標示其係拒用物品，並分別儲存於限制區中。該物品應退回供應商，或於合適時，予以重處理或銷毀。不論採取任何行動皆應經被授權人員的認可並予記錄。	5.61	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.
5.62	拒用產品的重處理應屬例外。該重處理僅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，依界定且經核准的程序執行時方始允許，且其紀錄應予保存。	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.
5.63	符合所需品質之先前批次的全部或一部分，在界定的製造階段，併入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，依界定的程序執行之。該收回應予記錄。	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.

5.64	經過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試驗的必要性。	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.
5.65	從市場退回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面程序嚴格評估後，始得考慮重新銷售、重新標示或是併入下一批收回。這種評估中，產品的性質、所要求的任何特別儲存條件、其狀況及歷史，以及自銷出後已經過的時間等皆應列入考慮。縱使基本的化學重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。	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.

第六章 品質管制（QUALITY CONTROL）

原則（PRINCIPLE）	
本章應與 GMP 指引的所有相關部分一起研讀。	This chapter should be read in conjunction with all relevant sections of the GMP guide.
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，確保必要與相關的檢驗皆已執行，並確保在品質經判斷滿意前，無原物料會被放行供使用，無產品會被放行供銷售或供應。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所有決定。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。	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.
一般規定（GENERAL）	
6.1 每一個製造許可的持有者均應有品質管制部門。此部門應從其他部門獨立出來，並由具有適當資格及經驗的人員負責。該人員擁有可由其支配之一個或多個品管實驗室。此部門應有適當的資源，以確保有效且可靠地執行所有品質管制的安排。	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.

6.2	品質管制主管的主要職責概述於第二章。整體而言，品質管制部門亦有其他的職責，例如：制訂、確效並執行所有品質管制程序，監督原物料與產品之對照及/或留存樣品的管制（當適用時），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。這些作業皆應依書面程序執行，且在必要時，應予記錄。	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, oversee the control of the reference and/or retention samples of materials and products when applicable, ensure the correct labelling of containers of materials and products, ensure the monitoring of the stability of 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	最終產品的評價應包含所有相關的因素，包括生產條件、製程中檢驗的結果、製造（包括分/包裝）文件的檢討、符合最終產品規格及最終包裝產品的檢查。	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.
6.4	為抽樣與調查，合適時，品質管制人員應進入生產區。	6.4	Quality Control personnel should have access to production areas for sampling and investigation as appropriate.

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及特別的要求。實驗室設備應不得在高風險區域之間例行地移動，以避免意外的交叉污染。尤其是，微生物學實驗室應適當配置，以使交叉污染的風險減到最低。	6.5	Control laboratory premises and equipment should meet the general and specific requirements for Quality Control areas given in Chapter 3. Laboratory equipment should not be routinely moved between high risk areas to avoid accidental cross-contamination. In particular, the microbiological laboratory should be arranged so as to minimize risk of cross-contamination.
6.6	實驗室中的人員、廠房設施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。在符合第七章委外活動所詳述的原則下，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。	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, Outsourced Activities, can be accepted for particular reasons, but this should be stated in the Quality Control records.
文件（Documentation）			
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供品質管制部門易於取用：	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:
	(i) 規格；		(i) Specifications;
	(ii) 描述抽樣、檢驗、紀錄（包含檢驗工作單及/或實驗室筆記本）、記錄與確認的程序；		(ii) Procedures describing sampling, testing, records (including test worksheets and/or laboratory notebooks), recording and verifying;
	(iii) 儀器校正/驗證與設備維護保養的程序及紀錄；		(iii) Procedures for and records of the calibration/qualification of instruments and maintenance of equipment;

	(iv) 偏離規格及偏離趨勢結果的調查程序；		(iv) A procedure for the investigation of Out of Specification and Out of Trend results;
	(v) 檢驗報告及/或分析證明書；		(v) Testing reports and/or certificates of analysis;
	(vi) 環境（空氣、水與其他公用設施）監測數據/資料（要求時）；		(vi) Data from environmental (air, water and other utilities) monitoring, where required;
	(vii) 檢驗方法的確效紀錄（可行時）。		(vii) Validation records of test methods, where applicable.
6.8	與批次紀錄有關之任何品質管制文件的保存，應遵循第 4 章關於批次文件製作之原則。	6.8	Any Quality Control documentation relating to a batch record should be retained following the principles given in Chapter 4 on retention of batch documentation.
6.9	某些類型的數據（如：檢驗結果、產率、環境的管制）應以允許趨勢評估的方式記錄。任何偏離趨勢或偏離規格數據應提出並進行調查。	6.9	Some kinds of data (e.g. tests results, yields, environmental controls) should be recorded in a manner permitting trend evaluation. Any Out of Trend or Out of Specification data should be addressed and subject to investigation.
6.10	除列入批次文件之資訊外，其他原始數據，例如實驗室筆記本及/或紀錄，皆應予保存且易於取用。	6.10	In addition to the information which is part of the batch documentation, other raw data such as laboratory notebooks and/or records should be retained and readily available.
抽樣（Sampling）			
6.11	抽樣應依經核准之書面程序執行及記錄。該程序描述下列項目：	6.11	The sample taking should be done and recorded in accordance with approved written procedures that describe:
	(i) 抽樣的方法；		(i) The method of sampling;
	(ii) 使用的設備；		(ii) The equipment to be used;
	(iii) 抽取的樣品量；		(iii) The amount of the sample to be taken;
	(iv) 任何要求將樣品再細分的指令；		(iv) Instructions for any required sub-division of the sample;
	(v) 使用之樣品容器的類型及條件；		(v) The type and condition of the sample container to be used;

	(vi) 經抽取樣品之容器的識別；		(vi) The identification of containers sampled;
	(vii) 應遵行的任何特殊注意事項，特別是關於無菌的或有毒物質的抽樣；		(vii) Any special precautions to be observed, especially with regard to the sampling of sterile or noxious materials;
	(viii) 儲存條件；		(viii) The storage conditions;
	(ix) 抽樣設備之清潔與儲存的指令。		(ix) Instructions for the cleaning and storage of sampling equipment.
6.12	樣品對於其取自之原物料或產品批次應有代表性。用以監測製程之最困難的部分，亦可另取其他樣品（例如：製程的開始或結束）為之。所使用的抽樣計畫應基於風險管理方法，並適當地證明其合理性。	6.12	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). The sampling plan used should be appropriately justified and based on a risk management approach.
6.13	樣品容器的標籤應標示其內容物、批號、抽樣日期及樣品所取自之容器。它們應以使混雜的風險減到最低，並使樣品免於受到不良儲存條件的方式進行管理。	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. They should be managed in a manner to minimize the risk of mix-up and to protect the samples from adverse storage conditions.
6.14	關於對照樣品與留存樣品的進一步指引參照附則 19。	6.14	Further guidance on reference and retention samples is given in Annex 19.
檢驗（Testing）			
6.15	檢驗方法應予確效。非執行原始確效的實驗室，使用該檢驗方法時應確認其合適性。根據上市許可或技術檔案中所描述的所有檢驗作業皆應依經核定的方法執行之。	6.15	Testing methods should be validated. A laboratory that is using a testing method and which did not perform the original validation, should verify the appropriateness of the testing method. All testing operations described in the Marketing Authorisation or technical dossier should be carried out according to the approved methods.

6.16 獲得的結果應予記錄。經確認為關鍵品質屬性之參數的結果應進行趨勢分析及檢查/核對，以確保彼此間是一致的。任何計算均應予嚴格驗算。	6.16 The results obtained should be recorded. Results of parameters identified as critical quality attributes should be trended and checked to make sure that they are consistent with each other. Any calculations should be critically examined.
6.17 執行的試驗應予記錄且至少應包括下列數據/資料：	6.17 The tests performed should be recorded and the records should include at least the following data:
(i) 原物料或產品名稱，及其劑型（可行時）；	(i) Name of the material or product and, where applicable, dosage form;
(ii) 批號，及其製造廠及/或供應商（合適時）；	(ii) Batch number and, where appropriate, the manufacturer and/or supplier;
(iii) 相關規格與檢驗程序的參考資料；	(iii) References to the relevant specifications and testing procedures;
(iv) 檢驗的結果，包括觀察、計算及任何檢驗證明書的參考資料；	(iv) Test results, including observations and calculations, and reference to any certificates of analysis;
(v) 檢驗日期；	(v) Dates of testing;
(vi) 執行該檢驗之人員的簽名；	(vi) Initials of the persons who performed the testing;
(vii) 合適時，確認檢驗及計算結果之人員的簽名；	(vii) Initials of the persons who verified the testing and the calculations, where appropriate;
(viii) 核准或拒用（或其他狀態的決定）之清楚說明及指定之負責人員註明日期的簽章；	(viii) A clear statement of approval or rejection (or other status decision) and the dated signature of the designated responsible person;
(ix) 引述所使用的設備。	(ix) Reference to the equipment used.

6.18	所有製程中管制，包括由生產人員在生產區中所執行的管制，應依品質管制部門認可的方法執行，並記錄其結果。	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.
6.19	應特別注意實驗室試劑、溶液、玻璃器皿、對照標準品及培養基等之品質，並應依書面的程序製備與管制。管制的程度應與其使用及既有之安定性資料相稱。	6.19	Special attention should be given to the quality of laboratory reagents, solutions, glassware, reference standards and culture media. They should be prepared and controlled in accordance with written procedures. The level of controls should be commensurate to their use and to the available stability data.
6.20	對照標準品應經確認適合其預定用途，其驗證與認證應明確說明和記錄。當有公認來源的公定標準品存在時，應優先用作一級標準品，但如已有文件化證明二級標準品對一級標準品的可追溯性，則允許使用二級標準品。除主管機關另有授權外，這些公定物質應依適當個論中所描述的目的使用。	6.20	Reference standards should be established as suitable for their intended use. Their qualification and certification, as such, should be clearly stated and documented. Whenever compendial reference standards from an officially recognised source exist, these should preferably be used as primary reference standards unless fully justified (the use of secondary standards is permitted once their traceability to primary standards has been demonstrated and is documented). These compendial materials should be used for the purpose described in the appropriate monograph unless otherwise authorised by the National Competent Authority.

6.21	實驗室試劑、溶液、對照標準品與培養基應標記其配製與開封日期及配製人員的簽章。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	Laboratory reagents, solutions, reference standards and culture media should be marked with the preparation and opening date and the signature of the person who prepared them. The expiry date of reagents and culture 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.
6.22	必要時，應將用於檢驗作業之任何物質（例如：試劑、溶液及對照標準品）的接收日期標示在容器上。使用及儲存的指令應予遵循。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	Where necessary, the date of receipt of any substance used for testing operations (e.g. reagents, solutions 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.
6.23	除了科學上證明其合理性者外，培養基應依照培養基製造廠的要求製備。所有培養基的效能應在使用前加以確認。	6.23	Culture media should be prepared in accordance with the media manufacturer’s requirements unless scientifically justified. The performance of all culture media should be verified prior to use.
6.24	經使用後的微生物學培養基與菌株應根據標準程序進行去污染與處置，以防止交叉污染與殘留物之留存。配製後之微生物學培養基的架儲期應加以建立並文件化，且證明其科學合理性。	6.24	Used microbiological media and strains should be decontaminated according to a standard procedure and disposed of in a manner to prevent the cross-contamination and retention of residues. The in-use shelf life of microbiological media should be established, documented and scientifically justified.

6.25	用於檢驗組成物、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及管制，且應予識別與標示，並應保存顯示其使用歷程之適當紀錄。	6.25	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.
持續進行之安定性計畫（On-going stability programme）			
6.26	藥品上市後，其安定性應依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，在雜質含量，或溶離圖像描述的變化）。	6.26	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.
6.27	持續進行的安定性計畫之目的係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，該產品的品質仍可預期保持在其規格內。	6.27	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.

6.28	這主要應用於包裝藥品之販售，但亦應考慮將待分/包裝產品包括到計畫中。例如，當待分/包裝產品在包裝前及/或從製造場所裝運到包裝場所前，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，並在週遭的自然條件下研究之。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。然而，臨用調配之產品的安定性於合適時亦可以加以監測。	6.28	This mainly applies to the medicinal product in the package in which it is sold, 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.
6.29	持續進行之安定性計畫，應遵循第四章的一般規則，以書面計畫書描述之，並將其結果正式作成一份報告。使用於持續進行之安定性計畫的設備（尤其是安定性試驗箱/艙室）應依循第三章與附則 15 加以驗證並予維護。	6.29	The ongoing 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 ongoing stability programme (stability chambers among others) should be qualified and maintained following the general rules of Chapter 3 and Annex 15.
6.30	對於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，且應包括但不限於下列的參數：	6.30	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:
	(i) 每種含量與不同批量之批次數目（合適時）；		(i) Number of batch(es) per strength and different batch sizes, if applicable;

(ii) 相關的物理、化學、微生物學及生物學的檢驗方法；	(ii) Relevant physical, chemical, microbiological and biological test methods;
(iii) 允收標準；	(iii) Acceptance criteria;
(iv) 檢驗方法的參考資料；	(iv) Reference to test methods;
(v) 容器封蓋系統的描述；	(v) Description of the container closure system(s);
(vi) 測試間隔（時間點）；	(vi) Testing intervals (time points);
(vii) 儲存條件的描述（應使用與產品標示一致之標準化的 ICH 長期試驗條件）；	(vii) Description of the conditions of storage (standardised ICH/VICH conditions for long term testing, consistent with the product labelling, should be used);
(viii) 其他特別適用於該藥品的參數。	(viii) Other applicable parameters specific to the medicinal product.
6.31 若持續安定性計畫之計畫書中已證明其正當性並予以文件化者，得與當初在上市許可檔案中所提交之長期安定性試驗的計畫書不同（例如：測試頻率，或配合 ICH 之建議事項更新時）。	6.31 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/VICH recommendations).

6.32	批次數目與測試頻率應能提供足夠的數據量，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。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。	6.32	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.
6.33	某些情況，應在持續進行的安定性計畫中納入追加的批次。例如，製程或包裝有任何重大變更或重大偏差後，應執行持續進行的安定性研究。任何再加工、重處理或收回作業亦應考慮納入。	6.33	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.

6.34	持續進行之安定性試驗的結果，應使關鍵人員，特別是被授權人能夠取得。持續進行的安定性試驗係在待分/包裝或最終產品的製造場所外之另一個場所執行者，相關各方之間應有書面協議。在製造廠應可取得持續安定性試驗的結果，以備供主管機關檢查。	6.34	Results of on-going stability studies should be made available to key personnel 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.
6.35	有偏離規格或有顯著非典型趨勢時，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，對於已放行至市場之受影響的產品批次，應向主管機關提報，並應依優良製造規範指引第八章及與相關主管機關之研商結果，考慮對於市面上產品之批次可能造成的衝擊。	6.35	Out of specification or significant atypical trends should be investigated. Any confirmed out of specification result, or significant negative trend, affecting product batches released on the market 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.
6.36	產生之所有數據/資料的摘要，包含計畫中之任何暫時的結論在內，均應作成書面並予以保存。該摘要應定期檢討。	6.36	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.
檢驗方法的技術移轉（Technical transfer of testing methods）			

6.37 在移轉一個檢驗方法之前，移轉場所應確認該檢驗方法遵循上市許可或相關技術檔案中所描述的那些方法。檢驗方法之原始確效應進行再次審核，以確保遵循現行 ICH 要求。應執行並記錄差異分析，以確認在技術移轉過程開始之前應該執行的任何補充確效。	6.37 Prior to transferring a test method, the transferring site should verify that the test method(s) comply with those as described in the Marketing Authorisation or the relevant technical dossier. The original validation of the test method(s) should be reviewed to ensure compliance with current ICH/VICH requirements. A gap analysis should be performed and documented to identify any supplementary validation that should be performed, prior to commencing the technical transfer process.
6.38 檢驗方法從一個實驗室（移出實驗室）到另一個實驗室（接收實驗室）的移轉，應於詳細的計畫書中描述。	6.38 The transfer of testing methods from one laboratory (transferring laboratory) to another laboratory (receiving laboratory) should be described in a detailed protocol.
6.39 移轉計畫書應該包括但非侷限於下列參數：	6.39 The transfer protocol should include, but not be limited to, the following parameters:
(i) 待移轉之檢驗項目及相關檢驗方法之識別；	(i) Identification of the testing to be performed and the relevant test method(s) undergoing transfer;
(ii) 追加訓練要求的識別；	(ii) Identification of the additional training requirements;
(iii) 所要檢驗之標準品與樣品的識別；	(iii) Identification of standards and samples to be tested;
(iv) 檢驗品項之任何特別運送與儲存條件的識別；	(iv) Identification of any special transport and storage conditions of test items;
(v) 應基於方法學之現行確效研究以及關於 ICH 要求的允收標準。	(v) The acceptance criteria which should be based upon the current validation study of the methodology and with respect to ICH/VICH requirements.

6.40	在技術移轉過程結束之前，應進行與計畫書偏差的調查。技術移轉報告應將此比較結果予以文件化，適用時，並應確認檢驗方法需要進一步再確效的部分。	6.40	Deviations from the protocol should be investigated prior to closure of the technical transfer process. The technical transfer report should document the comparative outcome of the process and should identify areas requiring further test method revalidation, if applicable.
6.41	合適時，在其他指引中，對於特定檢驗方法（例如，近紅外線光譜法）之移轉所描述的特定要求，應加以論述。	6.41	Where appropriate, specific requirements described in other guidelines should be addressed for the transfer of particular testing methods (e.g. Near Infrared Spectroscopy).

第七章 委外活動（OUTSOURCED ACTIVITIES）

原則（PRINCIPLE）			
	GMP 指引所涵蓋之任何委外活動應經適當界定、協議與管制，以避免因誤解而可能導致不滿意品質的產品或作業。委託者與受託者間必須有清楚訂定雙方角色與職責的書面契約。委託者之製藥品質系統應清楚規定，被授權人認可每批次產品放行之完整職責的行使方式。		Any activity covered by the GMP Guide that is outsourced should be appropriately defined, agreed and controlled in order to avoid misunderstandings which could result in a product or operation of unsatisfactory quality. There must be a written contract between the Contract Giver and the Contract Acceptor which clearly establishes the roles and responsibilities of each party. The Pharmaceutical Quality System of the Contract Giver must clearly state the way that the Authorised Person certifying each batch of product for release exercises his/her full responsibility.
一般規定（GENERAL）			
7.1	應有書面契約涵蓋與相關產品或作業有關之委外活動，及與該契約之任何有關的技術安排。	7.1	There should be a written contract covering the outsourced activities, the products or operations to which they are related, and any technical arrangements made in connection with it.
7.2	適用時，對委外活動之所有安排，包括在技術上或其他安排中所建議之任何變更，皆應符合現行法規及相關產品之上市許可。	7.2	All arrangements for the outsourced activities including any proposed changes in technical or other arrangements should be in accordance with regulations in force, and the Marketing Authorisation for the product concerned, where applicable.
7.3	上市許可之持有者與製造者不相同時，應考慮本章節所述之原則做出適當的安排。	7.3	Where the Marketing Authorisation holder and the manufacturer are not the same, appropriate arrangements should be in place, taking into account the principles described in this chapter.
委託者（THE CONTRACT GIVER）			

7.4 委託者的製藥品質系統應包括任何委外活動的管制與審查。委託者應確認備有程序，以確保對委外活動的管制負最終責任。這些程序應包括品質風險管理原則，並且特別包括：	7.4 The Pharmaceutical Quality System of the Contract Giver should include the control and review of any outsourced activities. The Contract Giver is ultimately responsible to ensure processes are in place to assure the control of outsourced activities. These processes should incorporate quality risk management principles and notably include:
7.4.1 在委外活動進行前，委託者應負責評估受託者成功履行委外活動的合法性、合適性及能力。委託者也負責藉由該契約，確保本指引所闡釋之優良製造規範的原則與指引受到遵循；	7.4.1 Prior to outsourcing activities, the Contract Giver is responsible for assessing the legality, suitability and the competence of the Contract Acceptor to carry out successfully the outsourced activities. The Contract Giver is also responsible for ensuring by means of the contract that the principles and guidelines of GMP as interpreted in this Guide are followed;
7.4.2 委託者應提供受託者所有必需的資訊及知識，以使其依產品相關的現行法規及上市許可，正確地履行約定的作業。委託者應確保受託者完全認知與本產品或工作有關之任何可能會對其廠房設施、設備、人員、其他原物料或其他產品造成危害的問題；	7.4.2 The Contract Giver should provide the Contract Acceptor with all the information and knowledge necessary to carry out the contracted operations correctly in accordance with regulations in force, and the Marketing Authorisation for the product concerned. 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/her premises, equipment, personnel, other materials or other products;

7.4.3 委託者應監督與檢討受託者的表現，以及識別與實施任何需要的改進。	7.4.3 The Contract Giver should monitor and review the performance of the Contract Acceptor and the identification and implementation of any needed improvement.
7.5 委託者應負責審查及評估與委外活動相關之紀錄與結果。無論是由委託者親自或基於受託者之被授權人的確認，委託者應確保受託者所交付之所有產品及原物料皆依 GMP 及上市許可進行處理。	7.5 The Contract Giver should be responsible for reviewing and assessing the records and the results related to the outsourced activities. He/she should also ensure, either by himself/herself, or based on the confirmation of the Contract Acceptor's Authorised Person, that all products and materials delivered to him/her by the Contract Acceptor have been processed in accordance with GMP and the Marketing Authorisation.
受託者（THE CONTRACT ACCEPTOR）	
7.6 受託者應能令人滿意地執行委託者所託付的工作，例如有適當的廠房設施、設備、知識、經驗及能勝任的人員。	7.6 The Contract Acceptor must be able to carry out satisfactorily the work ordered by the Contract Giver such as having adequate premises, equipment, knowledge, experience, and competent personnel.
7.7 受託者應確認所被交付的所有產品、原物料與知識皆符合其預定之目的。	7.7 The Contract Acceptor should ensure that all products, materials and knowledge delivered to him/her are suitable for their intended purpose.

7.8	受託者未經委託者之事先評估及同意，不得將契約所委託的任何工作轉委託給第三方。受託者與任何第三方間所做的安排，應確保包含來自第三方之合適性評估的資訊及知識，以原委託者與受託者間約定的相同方式提供之。	7.8	The Contract Acceptor should not subcontract to a third party any of the work entrusted to him/her 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 information and knowledge, including those from assessments of the suitability of the third party, are made available in the same way as between the original Contract Giver and Contract Acceptor.
7.9	受託者不應做合約條款以外未經授權之變更，因其可能對委託者之委外活動造成品質不良的影響。	7.9	The Contract Acceptor should not make unauthorised changes, outside the terms of the Contract, which may adversely affect the quality of the outsourced activities for the Contract Giver.
7.10	受託者應瞭解委外活動（包含檢驗等）可能會受到主管機關之檢查。	7.10	The Contract Acceptor should understand that outsourced activities, including contract analysis, may be subject to inspection by the competent authorities.
契約（THE CONTRACT）			

7.11	委託者與受託者間應簽訂契約。該契約明定雙方關於委外活動的個別責任及溝通程序。契約中的技術層面應由具有相關委外活動及優良製造規範之適當知識的勝任人員擬定。委外活動的所有安排均應依產品相關之現行法規及上市許可的規定，並為雙方所同意。	7.11	A contract should be drawn up between the Contract Giver and the Contract Acceptor which specifies their respective responsibilities and communication processes relating to the outsourced activities. Technical aspects of the contract should be drawn up by competent persons suitably knowledgeable in related outsourced activities and Good Manufacturing Practice. All arrangements for outsourced activities must be in accordance with regulations in force and the Marketing Authorisation for the product concerned and agreed by both parties.
7.12	契約中應清楚載明執行委外活動之每一步驟何方負有責任，例如，知識管理、技術移轉、供應鏈、轉委託、原物料之品質與採購、原物料之檢驗及放行、從事生產及品質管制（包含製程中管制、抽樣及檢驗）。	7.12	The contract should describe clearly which party to the contract has responsibility for conducting each step of the outsourced activity, e.g. knowledge management, technology transfer, supply chain, subcontracting, quality and purchasing of materials, testing and releasing materials, undertaking production and quality controls (including in-process controls, sampling and analysis).
7.13	所有委外活動之相關紀錄應由委託者保存，或可為委託者取得，例如：製造、檢驗及運銷之紀錄及對照樣品。當有申訴或懷疑有瑕疵或調查涉及偽造產品時，應能取得任何與產品品質評估有關的任何紀錄，並應明定於委託者之相關程序中。	7.13	All records related to the outsourced activities, e.g. 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 or to investigating in the case of a suspected falsified product must be accessible and specified in the relevant procedures of the Contract Giver.

7.14	契約應明訂容許委託者稽查受託者所執行或雙方同意之轉委託商所執行的委外活動。	7.14	The contract should permit the Contract Giver to audit outsourced activities, performed by the Contract Acceptor or their mutually agreed subcontractors.

第八章 申訴與產品回收（COMPLAINTS AND PRODUCT RECALL）

原則（PRINCIPLE）			
	所有申訴及其他可能之瑕疵產品有關的資訊，均應遵循書面的程序詳實審核。為對所有意外事件作準備，應設計一套系統，以便必要時，能立即且有效地自市場回收已知或懷疑其有瑕疵的產品。		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.
申訴（COMPLAINTS）			
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。該指定人員若非被授權人員，應使被授權人員知悉任何申訴、調查或回收事宜。	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.
8.2	若涉及可能之產品瑕疵的申訴，應有書面的程序描述要採取的行動，包括考慮回收的需要。	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.
8.3	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。	8.3	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.
8.4	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，以確定其是否也受到影響。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。	8.4	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.
8.5	因申訴而做之所有決定與採取之措施應予記錄，並對照其對應的批次紀錄。	8.5	All the decisions and measures taken as a result of a complaint should be recorded and referenced to the corresponding batch records.
8.6	申訴紀錄應定期檢討，以發現需注意及可能造成已上市產品回收之特定或重發性問題的任何跡象。	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.
8.7	應特別注意確立申訴是否因仿冒所引起。	8.7	Special attention should be given to establishing whether a complaint was caused because of counterfeiting.
8.8	藥廠若由於可能有製造瑕疵、產品變質、發現仿冒品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。	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.
回收（RECALLS）			
8.9	應指定人員負責回收之執行與協調，並應給予足夠的支援人力，以適切迅速的程度處理所有回收事宜。該負責人員通常應與銷售部門相互獨立且該人員並非被授權人員者，應使被授權人員知悉任何回收作業。	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.
8.10	為有效的組織任何回收作業，應建立書面的程序、定期檢查/核對，且於必要時予以更新。	8.10	There should be established written procedures, regularly checked and updated when necessary, in order to organise any recall activity.
8.11	回收作業應能立即且在任何時候啟動。	8.11	Recall operations should be capable of

			being initiated promptly and at any time.
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所有國家的主管機關。	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.
8.13	運銷紀錄應易為負責回收的人員取得，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。	8.13	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.
8.14	回收的產品在等候決定其最終處置方式的期間中，應予識別與標示並隔離儲存於安全區域。	8.14	Recalled products should be identified and stored separately in a secure area while awaiting a decision on their fate.
8.15	回收過程之進度應予記錄並提出最終報告。該報告應包含送交產品與收回產品的數量調和。	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.
8.16	回收作業之安排的有效性應予定期評估。	8.16	The effectiveness of the arrangements for recalls should be evaluated regularly.

第九章 自我查核（SELF INSPECTION）

原則（PRINCIPLE）			
	為監測優良製造規範原則之實施與遵守，應執行自我查核，並就必要的矯正措施提出建議。		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.
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。	9.1	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.
9.2	自我查核應由公司指定能勝任的人員，以獨立且詳細的方式執行。外部專家的獨立稽核可能也是有用的。	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.
9.3	所有自我查核應予記錄。報告應包含在檢查期間所執行之所有觀察，合適時，並含矯正措施的建議。後續採取之行動的說明亦應予記錄。	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.