保健營養食品業者優良製造作業(Good Manufacturing Practice , GMP)指引(草案)

	保健營養食品業者優良製造作業指引	Taiwan Guidelines on Good Manufacturing Practice for Health Supplements
	前言	**INTRODUCTION**
	保健營養食品業者優良製造作業(Good Manufacturing Practice, GMP)主要目的，期使業者生產時，其相關的品質保證(Quality Assurance, QA)系統，能涵蓋 GMP 及品質管制 (Quality Control, QC) 作業，確保製造之產品維持一定的品質。本指引提供保健營養食品業者執行品質管理作業流程之參考，為行政指導文件，各界可自行參酌運用。 製造是指從原料、半成品、成品，以及將成品以適合的形式加以包裝，並在產品包裝容器上標明成分、含量，及任何上述活動過程中所進行的任何程序，並涵蓋相關生產線的廠房設施及機器設備。 GMP 應在保健營養食品製造過程中實施，以便可以全面掌控及確保消費者獲得所預期的優質產品，本指引針對保健營養食品生產製造過程所應遵守的作業準則提供指導，雖然本指引並未針對新開發產品有所限制，但必要時，食品業者仍應提供製程中將採取的品質管控措施，以確保保健營養食品的安全和品質。 使用天然原料的保健營養食品，對於取自動物和植物體，易遭受傳染性疾病污染而變質等因素，在最開始的原料	The primary objective of Good Manufacturing Practice (GMP) of health supplements manufacturer is to ensure that quality assurance (QA) system can include GMP and quality control (QC) mechanism when manufacturers produce could ensure stable quality of products. The guidelines provide food manufacturers with reference when perform quality management process. It is an administrative guidance document and use by themselves. Manufacturing includes the production process from raw materials, semi-finished products, finished-products, and packaging final products to all the actions such as labeling ingredients and dosage on containers or relevant activities not mentioned above. It also covers premises, facilities and equipment of relevant production line. GMP shall be implemented in the manufacturing process of health food and supplements so that it can fully control and ensure that consumers receive the expected qualified products. This guideline as a guidebook gives many instructions for people to follow regarding manufacturing process of health supplements. Although this guideline does not intend to give any limitation for developing products, food industrials are supposed to provide quality control practice if necessary to ensure the safety and quality of health supplements. Those health supplements that use natural ingredients from animal or plants are easily to be contaminated and deteriorated in the process of production. Therefore, it shall take necessary

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	管控、保存、加工都應採取必要的措施，將危害因子降至可容許範圍以下。所使用的原料必需取得可供食品使用原料之證明，所有保健營養食品必需在嚴格的製程管理系統與品質監控條件下進行生產，成品檢驗只是品質管制的一環，並非最終目的。 本指引概述保健營養食品製造業者在相關製造過程中必須採取的作業步驟，目的在於確保其所製造的產品能達到其預期的品質。	practice to control initial raw materials, preservation and processing to minimize risk factors to an acceptable level of tolerance. Those raw materials shall be acquired with certification to prove that they are safe to use in food. All health supplements shall be produced under strict process management and quality control requirements. Finished product testing is only a part of quality control, not the ultimate purpose. This guideline is to outline necessary steps which shall be taken when it comes to the relevant production of health supplements by manufacturers. The main purpose is to ensure that their products could meet the expected quality requirements.
第一章	**品質管理**	**CHAPTER 1 - QUALITY MANAGEMENT**
一般原則		**PRINCIPLE**
	保健營養食品應在符合預期使用及國家主管機關規定之情形下被製造，以避免因不適當的安全性或品質造成消費者或病患健康相關之風險。品質目標必須是最高管理階層的責任，並要求各部門與各階層同仁以及原料供應商與下游通路商共同承諾與執行。為落實達到所宣示的品質目標，應有明確詳盡設計及落實執行的品質保證(QA)系統，包括：優良製造作業(Good Manufacturing Practice , GMP)及品質管制(QC)，應予以書面化並監督其實施成效，並有足以勝任之人員、適當且充分的廠房、機器設備與器具。	Health supplements shall be manufactured so as to ensure that they are fit for their intended use, comply with the requirements of the National Regulatory Authority (NRA) and do not place the health of the patients or consumers at risk due to inadequate safety and quality. The attainment of this quality objective is the responsibility of senior management and requires the participation and commitment by staff in many different departments and at all levels within the company, by the company's suppliers and by the distributors. To achieve the quality objective reliably there shall be a comprehensively designed and correctly implemented system of Quality Assurance incorporating Good Manufacturing Practice and thus Quality Control. It shall be fully documented and its effectiveness monitored. All parts of Quality Assurance system shall be adequately resourced with competent personnel, suitable and sufficient premises, equipment and facilities.
1.1	品質保證(QA)、優良製造作業(GMP)及品質管制(QC)是工廠內部相互關聯的系統，是生產及管制保健營養食品不可或缺的重要過程。	The basic concept of Quality Assurance, Good Manufacturing Practice and Quality Control are inter-related. They are described here in order to emphasise their relationships and their fundamental importance to the production and control of health supplements.

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品質保證		**QUALITY ASSURANCE (QA)**
1.2	品質保證是一個廣泛的概念，涵蓋所有影響產品品質的事項，其目的在確保產品具有預定的品質。品質保證包含 GMP 及本指引範圍以外的其他因素。製造保健營養食品的品質保證系統應確保：	Quality Assurance is a wide-ranging concept which covers all matters which individually or collectively influence the quality of a product. It is the sum total of the organized arrangements made with the object of ensuring the products are of the quality required for their intended use. Quality Assurance therefore incorporates Good Manufacturing Practice plus other factors outside the scope of these guidelines. The system of Quality Assurance appropriate for the manufacture of health supplements shall ensure that:
1.2.1	保健營養食品的設計及開發應符合 GMP 要求。	health supplements are designed and developed in a way that takes account of the requirements of Good Manufacturing Practice;
1.2.2	應明確規定生產與管制作業標準，並符合 GMP 要求。	production and control operations are clearly specified and Good Manufacturing Practice adopted;
1.2.3	應明確規定管理責任。	managerial responsibilities are clearly specified;
1.2.4	原料及包材之製造、供應及使用應加以適當安排。	arrangements are made for the manufacture, supply and use of the correct starting and packaging materials;
1.2.5	對於半成品和相關製程應加以管制。	all necessary controls on intermediate products, and any other in-process controls are carried out;
1.2.6	依所制定之程序進行成品的正確加工及查檢。	the finished product is correctly processed and checked, according to the defined procedures;
1.2.7	在每批產品之生產與管制應依產品註冊的要求及其他相關程序進行，在品質管理部門負責人確認之前，不能銷售。	health supplements are not sold or supplied before a head of Quality Control / Quality Assurance has certified that each production batch has been produced and controlled in accordance with the requirements of the NRA and any other procedures relevant to the production, control and release of health supplements;
1.2.8	建立適當的作業以確保保健營養食品的儲存、配送及後續處理，在有效日期之內其品質得以維持。	satisfactory arrangements exist to ensure, that the health supplements are stored, distributed and subsequently handled so that quality is maintained throughout their shelf life;
1.2.9	建立自主檢查的程序，以定期評鑑其 QA 系統之有效性與適用性。	there is a procedure for self-inspection and/or quality audit, which regularly appraises the effectiveness and applicability of the Quality Assurance system.
1.3	GMP 是 QA 的一部分， QA 是為了確保產品之製造與管制持續符合預期的規格及主管機關的規定；而 GMP 特別重視製程及品質管制。GMP 基本要求	Good Manufacturing Practice is that part of Quality Assurance which ensures that products are consistently manufactured and controlled to the quality standards appropriate to their intended use and as required by the NRA or product specification.

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	如下：	Good Manufacturing Practice is concerned with both production and quality control. The basic requirements of GMP are that:
1.3.1	界定製造過程，並依經驗進行系統性檢討，以顯示所生產的保健營養食品其品質持續符合其規格。	all manufacturing processes are clearly defined, systematically reviewed in the light of experience and shown to be capable of consistently manufacturing health supplements of the required quality and complying with their specifications;
1.3.2	製造過程的重要步驟及變動需經過查證(Verified)。	critical steps of manufacturing processes and significant changes to the process are verified;
1.3.3	實施 GMP 所需必要設施包括：	all necessary facilities for GMP are provided including:
1.3.3.1	合格及經過訓練的人員。	appropriate qualified and trained personnel;
1.3.3.2	適當的場所及空間。	adequate premises and space;
1.3.3.3	合適的設備與服務。	suitable equipment and services;
1.3.3.4	正確的原料、容器及標示。	correct materials, containers and labels;
1.3.3.5	核准的程序及作業標準。	approved procedures and instructions;
1.3.3.6	合適的倉庫與運輸。	suitable storage and transportation.
1.3.4	以明確的格式及用語制定程序書和作業標準。	instructions and procedures are written in an instructional form in clear and unambiguous language, specifically applicable to the facilities provided;
1.3.5	依制定的程序進行正確的操作與訓練。	operators are trained to carry out procedures correctly;
1.3.6	依程序書的規定進行每一步驟之操作，並以手寫或由紀錄儀進行紀錄，任何重大的偏差均應紀錄並加以調查發生原因，以證明及確保產品之成分(規格)及品質如預期。	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 products as expected. Any significant deviations are fully recorded and investigated;
1.3.7	包括配送的所有製造紀錄均應可追溯到每一生產批次，並保存於清晰且隨時可取得的狀態。	records of manufacture including distribution which enable the complete history of a batch to be traced, are retained in a comprehensible and accessible form;
1.3.8	配送過程應盡量降低影響品質的風險。	the distribution of the products minimizes any risk to their quality;
1.3.9	具備可隨時從市面上回收任一批次產品的回收機制。	a system is available to recall any batch of product, from sale or supply;
1.3.10	對產品相關的客訴應加以查核、調查造成缺失的原因，並採取適當處理與預防再發。	complaints about marketed products are examined, the causes of quality defects investigated and appropriate measures taken in respect of the defective products and to prevent recurrences.
品質管制(QC)		**QUALITY CONTROL (QC)**
1.4	QC 是 GMP 的一部分，包括抽	Quality Control is that part of Good Manufacturing

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	樣、規格與檢驗，透過建立組織、文件化與發佈程序書，以確保實際進行必要與相關的檢驗，在產品品質達到滿意之前，產品不應銷售或供應。QC 基本要求如下：	Practice which is concerned with sampling, specifications and testing, and with the organisation, documentation and release procedures which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their quality has been judged to be satisfactory. The basic requirements of Quality Control are that:
1.4.1	以適當的設備、經訓練的人員及核准的程序進行原料、包材、半成品、最終半成品及成品的抽樣、檢查及檢驗，並監控符合 GMP 之環境條件。	adequate facilities, trained personnel and approved procedures are available for sampling, inspecting and testing of starting materials, packaging materials, intermediate, bulk, and finished products, and where appropriate for monitoring environmental conditions for GMP purposes;
1.4.2	原料、包材、半成品、最終半成品及成品的取樣，由 QC 核准的人員及方式進行。	samples of starting materials, packaging materials, intermediate products, bulk products and finished products are taken by personnel and by methods approved by Quality Control;
1.4.3	檢驗方法需為主管機關公告、國際公認或其他經確效的方法。	test methods are either to be announced by the competent authority, internationally accepted or otherwise validated methods;
1.4.4	所有必要的抽樣、檢查及檢驗之紀錄（含手寫或紀錄儀紀錄）均確實紀錄，任何偏差亦須完整紀錄並加以調查。	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;
1.4.5	標示於產品包裝之營養素或特定成分應列為品管項目之一，並在容器包裝上明確標示其含量。	the finished products contain active materials complying with the qualitative and quantitative requirements of the NRA, are of the quality required, and are enclosed within their proper containers and correctly labelled;
1.4.6	原料、半成品、最終半成品及成品之檢查與檢驗結果的紀錄應經正式審查以確保符合規格。產品審查包括檢討與評估生產之相關文件與紀錄，並針對與程序不符之偏差進行審查。	records are made of the results of inspection and that testing of material, 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;
1.4.7	非經 QC 或 QA 主管核准的任何批次產品均不得販售。	no batch of product is released for sale or supply prior to certification by a head of QC / QA that it is in accordance with the requirements of the NRA;
1.4.8	建立足夠的原料和產品留樣，且產品須保存原包裝，除非生產特大包裝型式。	sufficient reference samples of starting materials and products are retained to permit future examination of the product if necessary and that the product is retained in its final pack unless exceptionally large packs are produced.

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產品品質檢討		**PRODUCT QUALITY REVIEW**
1.5	應有固定週期輪流進行保健營養食品的產品品質檢討，以查證加工過程的一致性及原料與成品規格的符合性，凸顯可能的趨勢及確認產品與製程的改進。產品品質檢討至少每年進行一次，並應考慮之前的評估作業，並至少包括：	Regular periodic or rolling quality reviews of all health supplements, including export only products, shall 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 shall normally be conducted and documented annually, taking into account previous reviews, and shall include at least:
1.5.1	檢討用於產品的原料及包材，特別是新的來源。	A review of starting materials and packaging materials used for the product, especially those from new sources.
1.5.2	對關鍵製程控制與成品品質結果的檢討。	A review of critical in-process controls and finished product results.
1.5.3	對未能達到規格的批次產品進行檢討及調查。	A review of all batches that failed to meet established specification(s) and their investigation.
1.5.4	檢討所有重大偏差與不符合的原因，及採取的矯正與預防措施之有效性。	A review of all significant deviations or non-conformances, their related investigations, and the effectiveness of resultant corrective and preventative actions taken.
1.5.5	對變更的製造過程或檢驗方法進行檢討。	A review of all changes carried out to the processes or analytical methods.
1.5.6	對有關產品授權提交、許可或拒絕的異動資料(包括輸出第三國的檔案)進行檢討。	A review of product authorization variations submitted/ granted/ refused, including those for third country (export only) dossiers.
1.5.7	檢討安定性試驗的結果及任何偏離值。	A review of the results of the stability monitoring programme and any adverse trends.
1.5.8	檢討與品質相關之退回品、客訴和產品回收及其調查過程。	A review of all quality-related returns, complaints and recalls and the investigations performed at the time.
1.5.9	充分檢討其他先前的製造過程或設備之矯正措施。	A review of adequacy of any other previous product process or equipment corrective actions.
1.5.10	相關設備和設施的維護情形，如空調、水、壓縮空氣等。	The qualification status of relevant equipment and utilities, e.g. Heating, Ventilation and Air Conditioning (HVAC), water, compressed gases, etc.
1.5.11	檢討技術協議合約，以確保未過期。	A review of Contractual Agreements to ensure that they are up to date.
1.5.12	當產品適用於查驗登記或其變更時，應進行上市後符合性之檢討。	A review of post-marketing commitment for new product/ variation.
1.6	工廠之管理階層應評估前項檢討之結果，並審查相關矯正與	The manufacturer and manufacturing authorization holder shall evaluate the results of this review and an assessment shall be made whether corrective

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	預防措施均已執行。矯正措施之原因應予以文件化。核准進行的矯正與預防措施應即時與有效。應針對上述措施加以管理與檢討並於自主檢查時查證其有效性。品質檢討可依產品的劑型(如固體劑型、液體劑型等)或種類以科學方法加以分群。	and preventive action shall be undertaken. Reasons for such corrective actions shall be documented. Agreed corrective and preventive actions shall be completed in a timely and effective manner. There shall 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, etc. where scientifically justified.
1.7	若產品擁有者非為製造者，二者應簽訂技術協議或合約，以確定執行品質檢討之雙方分別所負的責任。對最後產品批次負責者應與產品擁有者共同確保產品品質檢討即時進行並且準確。	Where the product owner is not the manufacturer, there shall be a technical agreement/ contract in place between the various parties that defines their respective responsibilities in producing the quality review. The authorised person responsible for final batch certification together with the product owner shall ensure that the quality review is performed in a timely manner and is accurate.
第二章	**人員**	**CHAPTER 2– PERSONNEL**
一般原則		**PRINCIPLE**
	工廠各階層均應有適當數量的人員，具備足以完成指定任務的知識與技能，且有良好適當的態度以執行 GMP。	There shall be an adequate number of personnel at all levels having knowledge, skill and capabilities relevant to their assigned function, and capable of handling their duties properly. They shall have the attitudes for achieving the goals of Good Manufacturing Practice (GMP)
組織、資格與權責		**ORGANISATION, QUALIFICATION AND RESPONSIBILITIES**
2.1	工廠應建立組織架構圖，並有書面的職責任務說明，若有指派代表或代理人，應有足夠的資格。生產製造部門與品質管理部門的主管應各自獨立，不可為同一人，也不對另一方負責，有足夠權力執行有效的職責。並應有適當的人員可根據已建立之程序及規格來製造和品管相關作業。	The manufacturer shall have an organisation chart. People in responsible positions shall 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 shall be no gaps or unexplained overlaps in the responsibilities of those personnel concerned with the application of Good Manufacturing Practice. The organisational structure of the company shall be such that the Production and the Quality Control Departments shall be independent of each other. Key posts shall be occupied by full-time personnel (direct supervision during operation) and shall be given full authority necessary to execute his/her duties effectively. An adequate number of trained personnel shall be

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		available to carry out the production and the quality control operations in accordance with established procedures and specifications.
2.2	生產製造部門負責人應接受充分訓練,具有執行 GMP 之經驗和足夠的知識製造保健營養食品。生產部門負責人管理生產產品的責任涵蓋營運、設備、生產人員、生產區和紀錄。其職責為：	The head of Production Department shall be adequately trained and possess good practical experience and adequate knowledge in manufacturing health supplements, which can enable to perform his functions effectively. The head of production department shall have full authority and responsibilities to manage production of products covering operations, equipment, production personnel, production area and records. The head of the production department generally has the following responsibilities:
2.2.1	確保產品按照製定程序進行生產和儲存，以符合品質。	to ensure those products are manufactured and stored according to the appropriate documentation in order to obtain the required quality;
2.2.2	核准有關生產作業的指示，包括過程中的控制和確保指示能被嚴格執行。	to approve the instructions relating to production operations, including the in-process controls and to ensure their strict implementation;
2.2.3	確保生產紀錄在提供給品質管理部門之前，由指定人員對生產紀錄進行評估和簽名。	to ensure that the production records are evaluated and signed by a designated person before they are made available to the Quality Control Department;
2.2.4	查檢各區域、建築與設備的維護情況。	to check the maintenance of the department, premises and equipment;
2.2.5	確保關鍵製程有適當的查證。	to ensure that the critical processes are appropriately verified;
2.2.6	確保對生產人員進行初始與持續的培訓,並依需要進行調整。	to ensure that the required initial and continuing training of production personnel is carried out and adapted according to need;
2.3	品質管理部門的負責人應有足夠的訓練和經驗，以能有效執行作業。其應被充分授權所有品質管制的職責，如建立、查證和實施所有品質管理程序，有權力核准原料、半成品、最終半成品、成品符合規格者及拒絕不符合規格者或在不按照核准的程序下製造者。其職責為:	The head of Quality Control Department shall have adequate training and practical experience, which can enable the person to perform the functions effectively. He/She shall be given full authority and responsibility in all quality control duties such as establishment, verification and implementation of all quality control procedures. He/She shall have the sole authority to approve starting materials, intermediates, bulk and finished products that meet the specification or to reject those which do not conform to the relevant specification or which were not manufactured in accordance with approved procedures and under the defined conditions. The head of Quality Control shall have the following responsibilities:
2.3.1	核准或拒絕原料、包材、半成品、最終半成品與成品。	to approve or reject starting materials, packaging materials and intermediate, bulk and finished

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		products;
2.3.2	評估每批次的紀錄。	to evaluate batch records;
2.3.3	確保進行所有必要的檢驗。	to ensure that all necessary testing is carried out;
2.3.4	確保關鍵製程得到適當的查證。	to ensure that the critical processes are appropriately verified;
2.3.5	核准採樣說明書、規格書、檢驗方法和其他品質管制程序。	to approve sampling instructions, specification, test methods, and other quality control procedures;
2.3.6	核准和監控依合約要求進行的檢驗。	to approve and monitor tests carried out under contract;
2.3.7	查檢建築、作業場所與設備的維護情況。	to check the maintenance of the department, premises and equipment;
2.3.8	依安定性試驗或與儲存條件相關的安定性試驗數據，建立符合產品規格之有效日期。	to establish expiration date and shelf life specifications on the basis of stability test or available stability data related to storage conditions;
2.3.9	核准能提供符合產品要求的品質標準之原料與包材供應商。	to approve those suppliers of raw materials and packaging materials who are capable of reliably supplying products meeting the company's established quality standards;
2.3.10	評估收到的任何客訴或任一批次產品的品質瑕疵，必要時應與其他部門聯合採取適當行動。	to evaluate all complaints received or deficiencies noted about any batch, if necessary in conjunction with other departments, and to take appropriate action accordingly;
2.3.11	保存足夠的檢驗紀錄及樣品查核紀錄。	to maintain adequate analytical records concerning the examinations of all samples taken;
2.3.12	為使產品符合規定的品質標準，可對委託製造者提供製造操作之建議。	to recommend contract-manufacturing operations which shall meet the company's specified quality standards;
2.3.13	確保對部門人員的初始與持續的教育訓練，並依需要進行調整。	to ensure that the required initial and continuing training of his department personnel is carried out and adapted according to need.
2.4	生產製造部門與品質管理部門負責人應共同承擔之責任:	The heads of Production Department and Quality Control Department shall share a joint responsibility:
2.4.1	確認書面程序書已制定並核准，其相關修正亦同。	to ensure that written procedures are established and to authorize written procedures and relevant document including amendments;
2.4.2	監督和控制製造環境之衛生。	to monitor and control the manufacturing environment, sanitation and hygiene;
2.4.3	查證關鍵製程。	to verify critical processes;
2.4.4	人員教育訓練。	to train personnel;
2.4.5	核准及監控原料供應商和委託製造者。	to approve and monitor the suppliers of materials and contract manufacturers;
2.4.6	建立與監控原料及產品的儲存條件。	to establish and monitor the storage conditions for materials and products;

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2.4.7	紀錄保存。	to retain records;
2.4.8	監控是否符合 GMP 的要求。	to monitor compliance with the requirements of Good Manufacturing Practice;
2.4.9	進行檢查、調查及抽樣，以監控可能影響產品品質的因素。	to inspect, investigate and take samples, in order to monitor factors which may affect product quality.
教育訓練		**TRAINING**
2.5	應有足夠已受訓的人員按照既定的程序與規格進行生產與品質管制作業操作。	All personnel shall be trained in the particular operations and in the principles of Good Manufacturing Practice.
2.6	應持續進行 GMP 教育訓練，確保員工符合與其職能相關的 GMP 要求，並應按照生產製造部門與品質管理部門主管核准的書面方案進行教育訓練。	Training in Good Manufacturing Practice shall be on a continuing basis and with adequate frequency to assure that employees remain familiar with Good Manufacturing Practices requirements relevant to their functions. Training in Good Manufacturing Practice shall be in accordance with written programmes approved by the head of Production Department and the head of Quality Control Department.
2.7	包括 GMP 等的教育訓練紀錄應適當保存，並定期審查訓練計畫的有效性。	Personnel training records including Good Manufacturing Practice shall be maintained and the effectiveness of training programs shall be assessed periodically.
2.8	應在訓練期間充分討論 QA 的觀念和所有相關措施，以讓員工充分了解並落實執行。	The concept of Quality Assurance and all the measures capable of improving its understanding and implementation shall be fully discussed during the training sessions.
第三章	**廠房設施與設備**	**CHAPTER 3 – PREMISES AND EQUIPMENT**
一般原則		**PRINCIPLE**
	廠房設施與設備應配合生產所需進行設置、設計、建造、修改及維護，盡量降低錯誤發生的風險並盡可能提高清潔與維護之效能，以降低交叉污染、產生粉塵或灰塵及任何造成產品品質不良之影響。	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 minimize 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**
一般要求		**GENERAL**
3.1	製造作業場所應具有合適尺寸、設計、結構和位置，以方便正常操作、清潔和保養。	Premises for manufacturing shall be of suitable size, design, construction and location to facilitate proper operation, cleaning and maintenance.
3.2	廠房應小心維護以確保修理或維護作業不會導致危害產品品質，且應依程序書進行應有之	Premises shall be carefully maintained, ensuring that repair and maintenance operations do not present any hazard to the quality of products. They shall be cleaned and, where applicable, disinfected

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	清潔與消毒作業。	according to detailed written procedures.
3.3	採取適當措施防止未經許可的人員進入。製造、儲存及品質管制之區域應避免不在其中工作的人員進入。	Steps shall be taken in order to prevent the entry of unauthorized people. Production, storage and quality control areas shall not be used as a right of way by personnel who do not work in them.
3.4	照明、溫度、濕度與通風應適當或正常運作，以確保不會直接或間接影響製造及儲存中之產品，以及設備之功能。	Lighting, temperature, humidity and ventilation shall be appropriate and such that they do not adversely affect, directly or indirectly, either the products during their manufacture and storage, or the accurate functioning of equipment.
3.5	廠房設置應經相關主管機關之核准。	Premises shall be located at a suitable site approved by the relevant authorities.
3.6	建築物的位置應避免周遭環境的污染，或能透過有效措施避免污染。	Premises shall 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.
3.7	為避免交叉污染，若生產特殊的保健營養食品(例如活菌)，應以專用設備生產，除非能確保該污染可以受到控制，始可考慮共用生產設備。廠房的設計應考慮避免不同產品或原料的摻混，以及與其他物質之交叉污染。	In order to minimize the risk of a serious hazard due to cross-contamination, dedicated and self-contained facilities must be available for the production of particular products such as highly sensitising materials (e.g. penicillins) or biological preparations medicinal products (e.g. from live micro-organisms i.e. these products shall not be produced in the same facilities used to produce Health Supplements. If Traditional Medicines and Health Supplements are sharing the same manufacturing facilities cross-contamination shall be adequately addressed (examples include but not limited to: by performing cleaning verification or the use of separate equipment, etc).
3.8	建築物應適當設計、建造及維護，防止蟲害、嚙齒動物、鳥類、昆蟲或其他動物的出入和窩藏。	Premises shall be designed, constructed and maintained to protect against access and harboring of vermin, rodents, birds, insects or other animals.
3.9	有可能受到其他危害或污染的原料處理或成品，其作業區必須與其他生產區域隔離。	Design shall consider prevention of mix-up between different products or their components and the possibility of cross contamination by other substances.
3.10	需特別注意加工時所產生的粉塵，應有合適的除塵及空氣處理系統，防止粉塵的產生和擴散。	Special attention must be given for processing operations that generate dust. Measures shall be taken to prevent the generation and dissemination of dust.
3.11	需定義以下的操作區域:	Defined areas for the following operations are required:
3.11.1	進貨與驗收區。	Receiving and quarantine of incoming materials
3.11.2	取樣區。	Sampling

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3.11.3	原料及包材儲存區。	Storage of starting and packaging materials
3.11.4	稱重與調配區。	Weighing /Dispensing
3.11.5	製造作業區。	Processing
3.11.6	半成品與最終半成品儲存區。	Storage of bulk/intermediate products
3.11.7	包裝區。	Packaging
3.11.8	設備清洗區。	Equipment washing
3.11.9	待驗成品的儲存區。 待驗品必須確保存放於特定獨立區域，並加以清楚標示，僅可由權責人員進出，若以其他方式取代實體驗收方式，應提供等同效果的保證。	Storage of quarantine finished products. Where quarantine status is ensured by storage in separate areas, these areas must be clearly marked and their access restricted to authorized personnel. Any system replacing the physical quarantine shall give equivalent security.
3.11.10	經核准之成品儲存區。	Storage of approved finished products
3.11.11	指定的品質管制區。	Designated area for quality control
製造作業區		***PRODUCTION AREAS***
3.12	原料處理、內包裝室、半成品室等區域之表面(牆壁、地板與天花板)應為平滑無裂縫，開放的接縫不得脫落顆粒物，並應能夠有效的清潔和消毒。 製造作業區域地板應由不透水材料製成，鋪設在平坦的表面，能及時有效的清除溢出物，牆壁是不透水、可清洗的表面，牆壁和地板之間的接合處的縫隙，應進行清潔。	Where starting and primary packaging materials, intermediate or bulk products are exposed to the environment, interior surfaces (walls, floors and ceilings) shall be smooth, free from cracks and open joints, and shall not shed particulate matter and shall permit easy and effective cleaning and, if necessary, disinfection. The coving of junctions between walls and floors in the production areas is encouraged to facilitate cleaning.
3.13	應避免開放的渠道，必要時不可過深，若需要的話，應便於清潔與消毒。使用合適的材料建築。排水口應有適當的阻攔異物裝置。	Any open channels shall be avoided, but if required they shall be shallow enough to facilitate cleaning and disinfecting. All drainage shall have trapped gullies.
3.14	建築物應有效的照明及通風，並有空氣調節。溫度、濕度及過濾的設施操作時應適當。	Buildings shall be effectively ventilated with air control facilities (including temperature, humidity and filtration), appropriate both to the operations undertaken within and to the external environment.
3.15	製造作業區域應該有良好的照明，特別是在進行線上目視檢查的區域。	Production areas shall be well lit, particularly where visual on-line controls are carried out.
3.16	製造作業區域的管道、燈具、通風口等設施應適當設計與裝置，避免以不易清理之凹槽方式安裝。最好可由製造作業區域外部即可進入。	Pipework, light fittings, ventilation points and other services shall be designed and sited to avoid the creation of recesses which are difficult to clean. As far as possible, for maintenance purposes, they shall be accessible from outside the manufacturing

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		areas.
3.17	外用與內用成品的生產須分開在不同作業區進行。	Separate areas shall be used for the production of finished products intended for external use or application and finished products intended for internal consumption solely.
3.18	原料的取樣、秤重、混合與加工操作時，無論何時產生之灰塵應可便於清洗，使用除塵系統或專用場所。	In cases where dust is generated (e.g. during sampling, weighing, mixing and processing operations, packaging of dry products), specific provisions shall be taken to avoid cross-contamination and facilitate cleaning.
3.19	保健營養食品的包裝區域應特別設計與排列以避免摻混或交叉污染。	Premises for the packaging of health supplements shall be specifically designed and laid out so as to avoid mix-ups or cross-contamination.
3.20	廠房中製造作業區域的設置順序應按照操作順序與所需清潔度排列，以符合清潔度的要求及避免交叉污染。	Premises shall 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.
3.21	廠房中應有適當的空間可以適合生產及有效率的工作流程，以避免擁擠及混亂。	Adequacy of working space, which shall allow orderly and logical placement of equipment and materials and to suit the operation, efficient flow of work, effective communication and supervision as well as to avoid crowding and disorders.
3.22	更衣室應緊鄰於製造作業區旁，並與製造作業區分開。	Changing rooms shall be directly connected to but separated from processing areas.
3.23	由更衣室進入製造作業區應有適當的手部清潔及(或)消毒設備。	Changing rooms into the production areas shall have adequate hand washing and / or sanitizing facilities.
倉庫		***STORAGE AREAS***
3.24	倉庫應有足夠空間以儲存不同類別的原料及產品：原料、包材、半成品、最終半成品、成品、待驗品、放行產品、退回品或回收品。	Storage areas shall 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 or recalled.
3.25	儲存區域應有適當的空間，提供適當的照明、動線和設施，在儲存材料和產品的放置上應保持乾燥、清潔與排列整齊。若有特殊儲存條件(如溫度、溼度等)的需求，應能提供查檢及監控。	Storage areas shall be designed or adapted to ensure good storage conditions. In particular, they shall be clean and dry and maintained within acceptable temperature limits. Where special storage conditions are required (e.g. temperature, humidity) these shall be provided, checked and monitored.
3.26	儲存區域應設置適當空間有效隔離被拒絕品、召回品、銷貨退回品。	Segregated and secure areas shall be provided for the storage of rejected, recalled or returned materials or products.
3.27	應有特殊和隔離的區域存放易	Highly active materials or products (e.g. flammable, explosive or toxic substances) shall be

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	燃、易爆物質、有毒物質以及被拒絕或召回的材料與產品。	stored in separate, safe and secure areas.
3.28	驗收與出貨區應有保護措施，以避免受天氣影響。收貨區的設計與裝備應可允許在儲存前，必要時對將填入物料的容器進行清潔。	Receiving and dispatch bays shall protect materials and products from the weather. Reception areas shall be designed and equipped to allow containers of incoming materials to be cleaned where necessary before storage.
3.29	取樣區應為獨立的，若是設在儲存區內，則亦應以獨立方式進行，以防止污染或交叉污染的可能性。	There shall normally be a separate sampling area for starting materials. If sampling is performed in the storage area, it shall be conducted in such a way as to prevent contamination or cross-contamination.
3.30	已印刷之外包材與其產品之符合性相當重要，應特別注意其包材儲存之安全及保全。	Printed packaging materials are considered critical to the conformity of the products, and special attention shall be paid to the safe and secure storage of these materials.
3.31	粗製(未經加工的)天然物原料應分開存放，儲存區應通風良好，並有病媒防治作業，採取有效措施以防止病媒帶來的發酵、發霉與交叉污染。容器放置的位置應可保持空氣流通。	Crude (i.e. unprocessed) natural materials shall be stored in separate areas. The store area shall be well ventilated and equipped in such a way as to give protection against insects, or other animals, especially rodents. Effective measures shall be taken to prevent the spread of any such animals and microorganisms brought in with the crude natural materials to prevent fermentation, mould growth and cross-contamination. Containers shall be located in such a way as to allow free air circulation.
3.32	儲存區域的維護，特別是當產生灰塵時，應注意清潔。	Special attention shall be paid to the cleanliness and good maintenance of the storage areas particularly when dust is generated.
3.33	原料或其他成分的儲存當需要特殊條件的溫度、濕度或光照保護時，應提供管制條件與監控作業。	Storage of plant materials, animal materials including parts, microorganisms, extracts, tinctures and other preparations that require special conditions of temperature, humidity or light protection; these conditions shall be provided and monitored.
品質管制區		***QUALITY CONTROL AREAS***
3.34	實驗室或品質管制的區域，應該與製造作業區域隔離，對於處理微生物之實驗室尤其重要。	If testing is done within the premises, quality control laboratories should be separated from production areas. This is particularly important for laboratories for the handling of microorganisms.
3.35	實驗室應適當設計以確保適合製造作業的檢驗活動，且應有足夠空間以避免混雜及交叉污染，另需有足夠的樣品及紀錄之儲存空間。	Control laboratories shall be designed to suit the operations to be carried out in them. Sufficient space shall be given to avoid mix-ups and cross-contamination. There shall be adequate suitable storage space for samples and records.
3.36	針對特別敏感的儀器應有專用	Separate rooms may be necessary to protect

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	空間以避免受到震動、電子干擾或濕度之影響。	sensitive instruments from vibrations, electrical interference, humidity, etc.
3.37	實驗室中之特殊操作，例如：微生物檢驗，應能符合其特殊操作之需求。	Special requirements are needed in laboratories handling particular substances such as microorganisms.
非食品處理區		***ANCILLARY AREAS***
3.38	員工休息室及廁所應與其他區域分開設置，且不得直接進入管制區域(例如製造作業區及倉庫)。	Rest and refreshment rooms and toilets shall be separated from other areas and shall not have direct access to controlled areas (e.g. production and storage areas).
3.39	員工更衣室、洗手設施及廁所之設置應容易使用且數量足夠。	Facilities for changing clothes, and for washing and toilet purposes shall be easily accessible and appropriate for the number of users.
3.40	設備維修區域應與製造作業區域分開設置。若有設備零件或工具需存放於製造作業區域中，必須有專櫃存放。	Maintenance workshops shall be separated from production areas. Whenever parts and tools are stored in the production area, they shall be kept in rooms or lockers reserved for that use.
3.41	實驗用動物房必須與其他區域隔離，且有不同之入口(動物通道)及空氣通風系統。	Animal houses shall be well isolated from other areas, with separate entrance (animal access) and air handling facilities.
設備		**EQUIPMENT**
3.42	製造作業設備的設計、放置及維護作業應符合其預期用途。	Manufacturing equipment shall be designed, placed and maintained to suit its intended use.
3.43	製造作業設備的安裝與拆卸應避免污染、遺漏或盡量降低風險，必要時進行檢驗以確保設備正常運作。	Manufacturing equipment shall be installed so as to prevent contamination or minimize the risk of error and, where necessary, tested to ensure the equipment operate appropriately.
3.44	製造作業設備應與其他設備保持一定距離，以避免交叉污染與擁擠。	Manufacturing equipment shall be located at a distance from other equipment sufficient to avoid congestion and cross contamination.
3.45	固定管路及閥組應明確標示其內容物及流向。	Fixed pipework shall be clearly labelled to indicate the contents and direction of flow.
3.46	天秤和測量設備應依製造作業及品管之需，具備適當之量測範圍及精度。	Balances and measuring equipment of an appropriate range and precision shall be available for production and control operation.
3.47	測量、秤重、紀錄儀和控制設備應定期以適當方法校正與查檢，並保存相關紀錄。	Measuring, weighing, recording and control equipment shall be calibrated and checked at defined intervals by appropriate methods. Adequate records of such activities shall be maintained.
3.48	製造作業設備應適當設計以利徹底清潔，並依相關程序書進行清潔，且應存放於乾淨與乾燥之環境。	Manufacturing equipment shall be designed so that it can be easily and thoroughly cleaned. It shall be cleaned according to detailed and written procedures and stored only in a clean and dry

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		condition.
3.49	用於製造僅供內部消費產品的設備應與用於製造外用或應用產品的設備分開。	Dedicated equipment used to manufacture products intended for internal consumption solely shall be separated from equipment used for the manufacturing of products intended for external use or application.
3.50	故障的設備應退出製造作業與品質管制區域，或至少要清楚標示為故障設備。	Defective equipment shall, if possible, be removed from production and quality control areas, or at least be clearly labelled as defective.
3.51	維修與保養操作不應對產品品質造成危害。若有零件遺失，如螺絲、彈簧、夾子等，應立即報告並調查。	Repair and maintenance operations shall not present hazard to the quality of the products. Any missing components such as nuts, springs, clips etc, shall be reported and investigated immediately.
3.52	製造作業設備及零件(包括輸送管路及軟管)不應對產品造成危害，與產品直接接觸的材質應是安定的，不得具有反應性、添加性或吸收性。	Production equipment (including transfer pipes and hoses) shall 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.
3.53	製程用水、原料、及產品之輸送管道、壓縮機及開關閥應依據程序書進行清洗與消毒，並註明該清潔方式對微生物污染之管制限值，及其所需採取之措施。	Pipes, hoses, pumps and valves used for treated water, starting materials and the products shall be cleaned and sanitised according to written procedures that detail the action limits for microbiological contamination and the measures to be taken.
第四章	**衛生管理**	**CHAPTER 4 – SANITATION AND HYGIENE**
一般原則		**PRINCIPLE**
	工廠應由各種角度來進行高規格的衛生管理，包括人員、廠房、設備及器具，以避免成為污染源。衛生管理的範圍包括：人員、廠房、設備及器具，以及任何有可能污染產品之污染源。所有人員應被教導並鼓勵立即向主管報告任何可能影響產品品質的問題或情形。	A high level of sanitation and hygiene shall be practised in every aspect of the manufacturing of health supplements. The scope of sanitation and hygiene covers personnel, premises, equipment and utensils; in fact, anything that could become a source of contamination to the product. All employees shall be instructed and encouraged to report to their immediate supervisor any conditions (plant, equipment or personnel) that they consider may adversely affect the quality of products.
人員		**PERSONNEL**
4.1	所有員工就業前應接受健康檢查，工作期間也應定期接受健康檢查，其中應包括所執行工	All personnel, prior to employment shall undergo health examinations. During the course of their employment they shall also routinely undergo health examinations which shall include relevant

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	作需要的相關檢查項目，如：眼睛定期檢查。	examinations appropriate to the tasks that they are required to perform.
4.2	所有員工均應執行良好個人衛生，並應被適當訓練，參與製程的所有人員應有高規格的衛生管理。	All personnel shall practise good personal hygiene. They shall be trained in the practices of personal hygiene. High level of personal hygiene shall be observed by all those concerned with manufacturing processes.
4.3	所有員工在任何時候出現可能對產品品質產生不利影響的明顯疾病或病變，在病情好轉之前，不得處理原料、包材、加工中材料和成品。	Any person shown at any time to have an apparent illness or open lesions that may adversely affect the quality of products shall not be allowed to handle raw materials, packaging materials, in-process materials, and finished products until the condition is improved.
4.4	員工的手與原料、半成品及最終半成品之間應避免直接接觸。如果與手接觸是不可避免的，應使用手套或適當的洗手。	Direct contact shall be avoided between the operator's hands and raw materials, intermediate or bulk product. Proper washing of hands and wearing of gloves shall be used if contact with hands is unavoidable.
4.5	為避免產品受污染及保護人員安全，應穿戴乾淨整齊適合執行工作之工作服。包括頭髮、鞋子。被污染的制服應置於密閉容器中，直至清洗乾淨。	To assure protection of the product from contamination as well as the safety of the personnel, appropriate protective garments shall be worn. Soiled uniforms shall be stored in closed containers until properly laundered.
4.6	只允許授權人員進入製造作業區域。訪客或未經培訓之人員，不應進入製造作業及品質管制之區域，若不可避免，應提前告知相關規定及提供工作服，並被嚴密監督。	Only authorised personnel shall be allowed to enter production areas. Visitors or untrained personnel shall, preferably, not be taken into the production and quality control areas. If this is unavoidable, they shall be given information in advance, particularly about personal hygiene and the prescribed protective clothing. They shall be closely supervised.
4.7	吸菸、飲食、咀嚼，食物、飲料、吸菸材料及個人藥物應限於特定區域，不得在製造作業區、實驗室、儲存區或其他可能會對產品品質有不利影響之區域有上述行為。	Smoking, eating, drinking and chewing or keeping of plants, food, drink, smoking materials and personal medicines shall be restricted to specific areas and not permitted in production, laboratory, storage or other areas where they might adversely influence product quality.
4.8	製造作業區域禁止人員化妝、配戴手錶或首飾，若首飾無法移除，則應予以適當防護並維持於清潔與衛生的狀態。	The wearing of makeup, wrist watches and jewellery shall be prohibited in the production area however for jewellery or objects that cannot be removed; it must be covered by material that is maintained in an intact, clean and sanitary condition.
廠房		**PREMISES**
4.9	用來製造產品的廠房應適當設計與建造，使能維持良好衛生狀態。	Premises used for the manufacturing of products shall be of suitable design and construction so as to facilitate good sanitation.

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4.10	應在適當地點設置足夠且通風良好的廁所、更衣室及洗手區，提供員工使用。	Adequate employee's washing and well ventilated toilet facilities and changing rooms shall be provided at suitable locations.
4.11	應在適當的位置提供儲物櫃，以便員工存放衣服和個人物品。	Suitable locker facilities shall be provided at appropriate locations for the storage of employees clothing and personal property.
4.12	員工飲食之製備、使用及儲存應限制在特定的區域，例如：員工餐廳，此區域應符合衛生標準，且不可由該區域直接進入管制區域(製造作業區及倉庫)。	The preparation, storage and consumption of food and beverages shall be restricted to specific areas, such as meal rooms and canteen. Facilities in such rooms must meet sanitary standards. Meal rooms and canteen rooms shall not have direct access to controlled areas (e.g. production area and areas use to store materials used for production and finished products).
4.13	廢棄物不可堆積，應收集於適當回收處，回收處應設置於建築物外部，且依衛生安全程序定期進行處理。	Waste material shall not be allowed to accumulate. It shall be collected in suitable receptacles for removal to collection points outside the buildings and disposed off safely and in a sanitary manner at regular and frequent intervals.
4.14	使用的殺鼠劑、殺蟲劑、燻蒸劑及消毒的材料不可污染設備、原料、包材及加工材料或成品。應有病媒防治計畫及文件，例如：配置圖、病媒趨勢及預期數量，必要時應有相關合約書。	Rodenticide, insecticides, fumigating agents and sanitising materials used must not contaminate equipment, raw materials, packaging materials, in-process materials or finished products. There shall be a pest control programme, documents such as layout, trending and expectations. Contract agreements shall be established, where applicable.
4.15	應有書面程序規定衛生、清潔責任，包括：頻率、方法及設備等。所使用的設備和材料應有書面程序說明，並遵循此程序進行清潔作業。	There shall be written procedures assigning responsibility for sanitation and describing cleaning schedules, methods, equipment, materials to be used and facilities to be cleaned in sufficient detail. Such written procedures shall be followed.
4.16	在製造工廠的範圍內不允許出現動物，包括：寵物。	Pets are not allowed within the vicinity of the manufacturing plant.
設備及器具		**EQUIPMENT AND UTENSILS**
4.17	設備與器具應內外清潔，於使用後按照標準作業程序存放，並保持其清潔狀態；在每次使用前應再查檢，以確保每批次產品安全。	Equipment and utensils shall be cleaned both inside and outside after use according to established procedures. Cleaned equipment shall be kept or stored in a clean condition and identified with the status of cleaning, and checked for cleanliness prior to each use.
4.18	盡量使用吸塵器或濕式清潔方法，若使用空壓機和毛刷等應小心使用，避免增加產品污染的風險。	Vacuum or wet cleaning methods are to be preferred. Compressed air and brushes shall be used with care or avoided if possible, as they increase the risk of product contamination
4.19	清潔劑、清洗及清潔設備不應成為污染源，並應選用適當的	Cleaning agents, washing and cleaning equipment shall not be a source of contamination. The choice

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	方式加以清潔。	of cleaning method and agents shall be carefully considered and justified.
4.20	應提供充足的儲存空間存放清潔藥劑與設備，最好與製造作業區域分開。	Adequate space, preferably separated from processing areas, shall be provided for cleaning and storing mobile equipment and utensils including the storage of cleaning materials.
4.21	建立並遵守有關設備、器具及容器等之清潔與消毒的程序。	Written procedures shall be established and followed for cleaning and sanitising of equipment, utensils and containers used in the manufacture of health supplements.
4.22	應建立程序書以防止設備被清潔劑與消毒劑污染，至少包括下列內容:	These procedures shall be prepared to prevent equipment contamination by cleaning or sanitising agents and shall at least include the following:
4.22.1	清潔的責任。	responsibility for cleaning,
4.22.2	清潔計畫。	cleaning schedule,
4.22.3	清潔方法。	cleaning methods,
4.22.4	用於清潔作業所使用的設備及材料。	methods of disassembling and reassembling equipment.
4.22.5	設備拆卸與安裝的方法。	methods of disassembling and reassembling equipment.
4.22.6	確認已去除前一批次產品的標示。	removal of previous batch identification
4.22.7	已完成清潔之設備和設施，在使用之前應加以保護。	protection of clean equipment and utensils from contamination prior to use
4.23	應紀錄清潔作業，包含消毒和使用前檢查。	Records of cleaning, including the appropriate sanitising and inspection conducted prior to use shall be maintained.
第五章	**文件**	**CHAPTER 5 – DOCUMENTATION**
一般原則		**PRINCIPLE**
	良好的文件管制是品質保證(QA)系統重要的一部分，良好的書面化作業可預防口語溝通的誤解，並能從原料到銷售過程中逐批追溯產品。應紀錄製造、倉儲、品管與配送及其他與 GMP 相關之作業。製造作業必須備有文件化的管理系統，涵蓋配方、作業方式、規格、程序書及紀錄，其內容必須正確且清晰。	Good documentation constitutes an essential part of the quality assurance system. Clearly written documentation prevents errors from spoken communication and permits tracing of batch history of the product, from purchasing of starting materials to the distribution of finished products. It shall be able to record executed activities for maintenance, storage, quality control, distribution and other specific matters linked to GMP. For manufacturing activities, a documentation system must be prepared. The system consisting of manufacturing formulae and instructions, specifications, procedures and records must be free from errors and clearly established.
一般要求		**GENERAL**

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5.1	文件系統應能紀錄並完整追溯每一批產品的所有紀錄，必要時可以調查並回溯任何有缺失的產品。	The system of documentation shall be able to record the complete history of each batch. It shall be adequate to permit investigation and tracing of any defective products.
5.2	文件應包括所有必要之資訊，任何的修改均應正式授權，並應定期檢討修正。	Documents shall contain all necessary information, to be kept up to date and any amendment shall be formally authorised. It shall include provision for periodic review and revision as necessary.
5.3	產品相關紀錄應留存至少 5 年。	Product related records shall be retained for at least five years after the expiry date of the finished product.
5.4	文件之發行、更新及廢止，必須經負責人或其授權人簽署，並核准實施，修訂時亦同，以確保執行品質作業人員持有最新且有效版本之作業文件，且文件應置於作業場所，以供作業人員易於查閱並據以執行。	Documents shall be designed, prepared, reviewed and distributed with care. The reproduction of working documents from master documents should not allow any error to be introduced to the reproduction process. Reproduced documents shall be clear, legible and duly authorised.
5.5	文件應由適當的授權人員批准、簽署，並註明簽署日期。	Documents shall be approved, signed and dated by appropriate and authorised person.
5.6	文件內容應明確，標題及目的應清楚陳述，並應有順序編排使容易查檢。	Documents shall have unambiguous contents; title, nature and purpose shall be clearly stated. They shall be laid out in an orderly fashion and easy to be checked.
5.7	文件應定期檢討並維持最新有效版本，修訂時應避免舊版本的文件被誤用。	Documents shall be regularly reviewed and kept up to date. When a document has been revised, systems shall be operated to prevent inadvertent use of superseded documents.
5.8	程序書等文件不得手寫，如實在必要，則須以不可消除的工具，如原子筆清晰書寫，且有一定間距，使不造成誤解。	Documents shall not be hand-written; although, where documents require the entry of data, these entries may be made in clear, legible, and indelible handwriting. Sufficient space shall be provided for such entries.
5.9	若以手寫進行文件修訂，需有簽名及日期，並紀錄修訂原因，且不得遮蔽原有文字。	Any alteration made to the entry on a document shall be signed and dated, and where appropriate the reason of the alteration to be recorded. The alteration shall permit the reading of the original information.
5.10	紀錄必須於每一實際操作時完成，使產品製作過程得以追溯。	The records shall be made or completed at the time each action is taken and in such a way that all significant activities concerning the manufacture the product are traceable.
5.11	紀錄可為電子化或拍照，但須有電子紀錄系統之程序且其紀錄之正確性應被查檢與查證，惟權責人員可進行存取或修正，且有明確的密碼管理，定	Data may be recorded by electronic data processing systems, photographic or other reliable means, but detailed procedure relating to the system in use shall be available and the accuracy of the records shall be checked and verified. If documentation is handled by electronic data

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	期備份，製程重要紀錄之輸入須能被獨立查檢與查證。	processing methods, only personnel who have been authorised shall be able to enter or modify data in the computer and there shall be a record of changes and deletions; access shall be restricted by passwords or other means and the result of entry of critical data shall be independently checked and verified. Batch records electronically stored shall be protected and back-up. It is particularly important that the data are readily available throughout the period of retention.
5.12	工廠應依程序書進行生產，若生產作業更動，則應修正相關程序書，且應據以進行人員教育訓練。	The manufacturer shall practice what is documented in the written procedures. Under circumstances where there is a change in the practice, the written procedures shall be promptly updated. On the other hand, if a written procedure was revised, appropriate training shall be provided to ensure that the personnel carry out the work in accordance to the revised procedure.
品質管制相關文件		**QUALITY CONTROL DOCUMENTS**
5.13	品質管制部門應隨時備有以下文件：	The following shall be readily available from the Quality Control Department:
5.13.1	規格。	Specifications
5.13.2	取樣程序書。	Sampling procedures
5.13.3	檢驗方法與紀錄(含檢驗紀錄及實驗紀錄簿)。	Testing procedures and records (including analytical worksheets and/or laboratory notebooks)
5.13.4	分析報告及(或)證書。	Analytical reports and/or certificates
5.13.5	環境監測值（必要時）。	Data from environmental monitoring, where appropriate.
5.13.6	儀器校正與設備維護的程序與紀錄。	Procedures for and records of the calibration of instruments and maintenance of equipment
5.14	品管相關文件與紀錄應留存至少 5 年。	Any Quality Control documentation relating to a batch record shall be retained for at least five years after the expiry date of the finished product.
規格		**SPECIFICATIONS E**
5.15	原料處理應適當且避免遭受交叉污染。所使用之原料及其供應商之品質紀錄應能被追溯，並隨時備查。	The materials used in the product shall be handled in an appropriate manner and manufactured in an appropriate controlled condition to prevent cross contamination. Documented traceability of the material and suppliers is fundamental to the quality of the finished products and shall be made available.
天然材料規格		***SPECIFICATIONS FOR NATURAL MATERIALS***
5.16	天然物原料規格必要時需包括：	The specifications for natural material shall where appropriate include the following:
5.16.1	學名，若可能列出命名者。	Scientific name and if possible with reference to the authors.

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5.16.2	天然物來源：產地、品種、收穫時間、採集方式、農藥之使用情形。	Details to the source of the natural material (country or region of origin, and where applicable, cultivation, time of harvesting, collection procedures, possible pesticides used, etc.).
5.16.3	是使用全部或部分植物或動物。	Whether the whole plant/animal or only a part is used.
5.16.4	若為向外採購者須明確瞭解其乾燥方式。	When dried plant/animal is purchased, drying system shall be specified.
5.16.5	天然物可佐以相片圖示或以放大鏡或顯微鏡進行檢測。	Pictorial demonstration/description of natural material, macroscopical and/or microscopical examination.
5.16.6	有儲存方式。	Storage conditions and precautions, when necessary.
5.16.7	有效期限。	Shelf life, where applicable
5.17	應進行適當之天然物檢驗，並有其檢驗程序，包括：	Testing procedures shall be available if the following tests are conducted, where appropriate.
5.17.1	鑑定方法包括檢驗其活性物質或指標成分。	Identification tests including, where possible, tests for known active constituents, or markers.
5.17.2	已知處方活性或指標成分的檢驗方式。	Assay, where possible, of constituents of known therapeutic activity or markers.
5.17.3	具管制界限的檢驗，如：灰份、精油含量及其經乾燥減少的含量。	Limit tests such as ash value, and presence of essential oils and loss on drying.
5.17.4	重金屬、可能的污染物、夾雜物、摻偽之檢驗。	Tests for heavy metals and for likely contaminants, foreign materials and adulterants.
5.17.5	放射線、黴菌毒素、微生物如黴菌與其他微生物之檢驗。	Tests for radioactivity, mycotoxin, fungal and microbial contamination.
5.17.6	萃取物或成品之溶劑殘留之檢驗。	Test for residual solvents in extracts or finished products, where applicable.
5.17.7	其他必要之檢驗。	Other tests, as required.
原料和包材之規格		***SPECIFICATIONS FOR STARTING MATERIALS AND PACKAGING MATERIALS***
5.18	原料及包材的規格必要時應包括：	Specifications for starting materials and packaging materials shall include, if applicable. When, starting material is a natural material, please refer to paragraph 5.17.
5.18.1	原料敘述，包括：	a description of the materials, including:
5.18.1.1	品名及其內部參考代碼。	the designated name and the internal code reference;
5.18.1.2	參考標準品。	the reference, if any, to a pharmacopoeia monograph;
5.18.1.3	核准之供應商，若可能最好是原始生產者	the approved suppliers and, if possible, the original producer of the products;
5.18.1.4	產品包材之印刷樣稿。	a specimen of printed materials;
5.18.2	取樣方式與檢驗方法。	directions for sampling and testing or reference to

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		procedures;
5.18.3	驗收標準應有定量及定性的標準。	qualitative and quantitative requirements with acceptance limits;
5.18.4	儲存方式。	storage conditions and precautions;
5.18.5	重新檢查前最長保存期。	the maximum period of storage before re-examination
半成品和最終半成品之規格		***SPECIFICATIONS FOR INTERMEDIATE AND BULK PRODUCTS***
5.19	當半成品或最終半成品被購買或運送，或半成品之檢驗將作為成品品質之評估，則應具備半成品或最終半成品規格，該規格應相或同於原料或成品。	Specifications for intermediate and bulk products shall be available if these are purchased or transferred, or if data obtained from intermediate products are used for the evaluation of the finished product. The specifications shall be similar to specifications for starting materials or for finished products, as appropriate.
成品規格		***SPECIFICATIONS FOR FINISHED PRODUCTS***
5.20	成品規格必要時應包含下列檢驗：	The specifications for finished product where appropriate shall include the following tests:
5.20.1	微生物限量標準。	Microbial limits;
5.20.2	重金屬限量標準。	Heavy metals limits;
5.20.3	重量均勻性(膠囊或錠劑產品)、崩散性(膠囊、錠劑或丸劑產品)、硬度及脆度(錠劑產品)、黏度(內部及外部液體)。	Uniformity of weight (for tablets and capsules), disintegration (for tablets, capsules and pills), hardness and friability (for tablets), and viscosity (for internal and external liquids);
5.20.4	物理性外觀如顏色、口味、質地、大小等。	Physical appearance such as colour, taste, texture, size, etc.
5.20.5	其他必要之檢驗。	Other tests, as required
5.21	規格亦應包括：	The specifications shall also include:
5.21.1	產品名稱及內部參考代碼。	The designated name of the product and the internal code reference where applicable;
5.21.2	配方或其參考文獻。	The formula or a reference to;
5.21.3	劑型及其包裝方式描述。	A description of the dosage form and package details;
5.21.4	取樣及檢驗方式，必要時列出其依據。	Directions for sampling and testing or a reference to procedures, where applicable;
5.21.5	定性與定量的要求，必要時，敘明限量標準。	The qualitative and quantitative requirements, with the acceptance limits, where applicable;
5.21.6	倉儲條件，必要時敘明特別的操作注意事項。	The storage condition and any special handling precautions, where applicable;
5.21.7	有效日期。	The shelf life
生產文件		**PRODUCTION DOCUMENTS**
製造配方和加工說明		***MANUFACTURING FORMULA AND PROCESSING INSTRUCTIONS***
	核准之製造配方與操作標準應	Formally authorised Manufacturing Formula and

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	存在於每批生產之產品，通常可合併為一份文件。	Processing Instructions shall exist for each product and batch size to be manufactured. They are often combined in one document.
5.22	製造配方包括：	The Manufacturing Formula shall include:
5.22.1	產品名稱及內部參考代碼。	The name of the product, with a product reference code relating to its specification;
5.22.2	劑型、批量、力價之描述。	A description of the product dosage form, strength of the product and batch size;
5.22.3	列出所有使用的原料，各原料之名稱應使用其特定名稱及其依據，對於因加工過程而隱沒之原料，應特別加以註明。	A list of all starting materials to be used, with the amount of each, described using the designated name and a reference which is unique to that material; mention shall be made of any substance that may disappear in the course of processing;
5.22.4	應敘明在符合限量標準之情形下的產率，必要時相關半成品之產率。	A statement of the expected final yield with the acceptable limits, and of relevant intermediate yields, where applicable.
5.23	製造作業相關作業標準應包括：	The Processing Instructions shall include:
5.23.1	各製造作業之位置及主要設備。	A statement of the processing location and the principal equipment to be used;
5.23.2	該設備之設定方式及其參考依據(如清潔、組裝、校正)。	The methods, or reference to the methods, to be used for setting up the equipment (e.g. Cleaning, assembling, calibrating);
5.23.3	詳細的加工步驟(如原料查檢、前處理、投料順序、混合時間、溫度)。	Detailed stepwise processing instruction (e.g. Checks on materials, pre-treatments, sequence for adding materials, mixing times, temperatures);
5.23.4	每一製程管制的作業標準及其限量。	The instructions for any in-process controls with their limits;
5.23.5	必要時應詳列最終半成品儲存條件，含容器、標示、特別儲存的條件。	Where necessary, the requirements for bulk storage of the products; including the container, labelling and special storage conditions where applicable;
5.23.6	其他注意事項。	Any special precautions to be observed.
5.24	應有作業標準針對原料不同的操作作業明確描述，如：分級、清潔、乾燥、粉碎、篩分，並含如乾燥時間與溫度、粉碎後之大小，且應描述如何透過篩分或其他方法來去除異物。	The processing instructions shall describe the different operations carried out upon the crude material such as sorting, cleaning, drying, crushing and sifting, and include drying time and temperatures, and methods used to control fragment or particle size. It shall also describe the sieving process or other methods of removing foreign materials.
5.25	應有作業標準及其紀錄，以確保產品包裝前其包材已查核不含異物如金屬異物、玻璃碎片…等。	In particular, there shall be written instructions and records, which ensure that each container of the product is carefully examined to detect any adulteration/substitution or presence of foreign matter, such as metal or glass pieces, animal parts or excrement, stones, sand, etc., or rot and signs

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		of decay.
5.26	針對產品之生產，應有作業標準描述相關萃取作業使用之溶劑、時間與溫度，及其濃縮或其他方法之作業方式。	For product preparation, instructions shall include details of base or solvent, time and temperatures of extraction, details of any concentration stages and methods used.
包裝作業標準		**PACKAGING INSTRUCTIONS**
5.27	應針對每項產品制定包裝作業標準，不同產品，包裝大小及種類應有個別包裝操作標準，包括：品名、劑量、包材種類、包材重複使用的規範、包裝前之清潔、包裝作業說明、線上品管取樣方式，且應包括或提及以下內容：	There shall be formally authorised Packaging Instructions for each product, pack size and type. These shall normally include, or have a reference to the following:
5.27.1	產品名稱。	Name of the product;
5.27.2	劑型描述和使用說明。	Description of its product dosage form, and strength where applicable;
5.27.3	包裝含量，敘明最後包裝方式之數量、重量或體積。	The pack size expressed in terms of the number, weight or volume of the product in the final container;
5.27.4	列出每一標準批量所需之包材，含數量、尺寸、種類及其內部參考代碼。	A complete list of all the packaging materials required for a standard batch size, including quantities, sizes and types, with the code or reference number relating to the specifications of each packaging material;
5.27.5	必要時列出範例或樣品，以說明包材重工時，批號之設定或產品有效期限之設定。	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;
5.27.6	包裝作業開始前應特別注意生產線之查核，確定無不必要之任何物品。	Special precautions to be observed, including a careful examination of the area and equipment in order to ascertain the line clearance before operations begin;
5.27.7	應有包裝作業操作標準，含重要操作步驟及其使用之機器。	A description of the packaging operation, including any significant additional operations, and equipment to be used;
5.27.8	製程作業管制細節，應說明取樣及可接受的極限。	Details of in-process controls with instructions for sampling and acceptance limits.
批次加工紀錄		**BATCH PROCESSING RECORDS**
5.28	應有「批次加工紀錄表」，作為批次製造作業紀錄的一部分，每批生產均應紀錄批號，並依核准之配方及操作標準如實紀錄，同時避免轉錄造成錯誤。	Batch Processing Record is that part of Batch Manufacturing Record and shall be kept for each batch processed. It shall be based on the relevant parts of the currently approved Manufacturing Formula and Processing Instructions. The method of preparation of such records shall be designed to avoid transcription errors. The record shall carry the batch number of the product being

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		manufactured.
5.29	生產前應進行查證並予以紀錄，以確定沒有前批留下之產品、原料及非必需之物品、文件，以及設備已完成清潔作業，可供後續生產。	Before any processing begins, there shall be recorded verification 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.
5.30	生產中應依規定即時並如實紀錄，需簽名且紀錄日期：	During processing, the following information shall be recorded at the time each action is taken and, after completion, the record shall be dated and signed in agreement by the person responsible for the processing operations:
5.30.1	品名。	The name of the product;
5.30.2	重要作業的起始及完成時間。	Dates and times of initiation, of significant intermediate stages and of completion of production;
5.30.3	每一步驟負責人。	Name of the person responsible for each stage of production;
5.30.4	每一重要步驟的操作人員與其製程管制人員。	Date and the signature of the operator of different significant steps of production and, where appropriate, of the person who checked each of these operations (e.g. Weighing);
5.30.5	每批原料應確實秤量，並紀錄該批次批號與數量及其品管數量。	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 materials added);
5.30.6	相關操作方式及使用之設備。	Any relevant processing operation or event and major equipment used;
5.30.7	加工中品質管制紀錄及其執行人員簽名與紀錄日期。	A record of the in-process controls and the date and signature of the person(s) carrying them out, and the results obtained;
5.30.8	各重要加工製程階段之產率紀錄。	The product yield obtained at different and pertinent stages of manufacture;
5.30.9	配方或加工作業的異常情形，並經負責人員簽名。	Notes on special problems including details, with signed authorisation for any deviation from the manufacturing formula and processing instructions.
批次包裝紀錄		**BATCH PACKAGING RECORDS**
5.31	應有「批次包裝紀錄表」，作為批次製造作業紀錄的一部分，應依產品包裝作業標準進行，如實紀錄各批次作業，並予以留存，且應避免因轉錄而造成錯誤。最終半成品及包裝成品之批號及批量均應紀錄。	A Batch Packaging Record is part of Manufacturing Record and shall be kept for each batch or part of batch processed. It shall be based on the relevant parts of the Packaging Instructions and the method of preparation of such records shall be designed to avoid transcription errors. The record shall carry the batch number and the quantity of bulk product to be packed, as well as the batch number and the planned quantity of finished product that will be obtained.

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5.32	包裝前應進行查檢確認沒有前批留下之原料，及非必需之物品與文件，以及設備之清潔，並紀錄之。	Before any packaging operation begins, there shall be recorded checks that the equipment and work station are clear of previous products, documents, or materials not required for the planned packaging operations, and that equipment is clean and suitable for use.
5.33	包裝製程應紀錄下列工作完成時間，並由負責包裝人員簽名：	The following information shall be entered at the time each action is taken and, after completion, the record shall be dated and signed in agreement by the person(s) responsible for the packaging operations:
5.33.1	品名。	The name of the product;
5.33.2	各包裝操作日期與時間，若有污染發生之可能，該包裝作業應於當天完成。	The date(s) and times of the packaging operations; when there is the risk of contamination, the packaging activity shall be done within the day itself
5.33.3	每一包裝作業之負責人。	The name of the responsible persons carrying out the packaging operation;
5.33.4	不同重要的包裝作業之操作人員及日期。	The date and signature of the operators of the different significant steps;
5.33.5	確認包裝作業與其操作標準含加工中管制一致的查證紀錄。	Records of verification for identity and conformity with the packaging instructions including the results of in-process controls;
5.33.6	包裝作業之各項作業應詳加紀錄，包括：機器設備的參考依據及所使用之生產線。	Details of the packaging operations carried out, including references to equipment and the packaging lines used;
5.33.7	印刷包材的樣品應留存含批號、效期及是否過量印刷等。	Whenever possible, samples of printed packaging materials used, which include the batch/lot number, expiry date and any additional overprinting;
5.33.8	包裝作業發生異常應詳加紀錄，並知會製造作業權責人員。	Notes on any special problems or unusual events including details, with date and signed authorisation from the manufacturing formula and processing instructions;
5.33.9	印刷包材和最終半成品領用、使用、報廢、或返回倉庫等之數量應加以確認。	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.
標準作業程序（SOPS）及紀錄		**STANDARD OPERATING PROCEDURES (SOPS) AND RECORDS**
5.34	應有原料及包材驗收程序書及紀錄，驗收紀錄應包括：	There shall be written procedures and records for the receipt of each delivery of each starting materials and packaging material. The records of the receipts shall include:
5.34.1	在收貨文件及其容器上所標示的原料品名。	The name of material on the delivery note and the containers;
5.34.2	廠內所用之原料名稱及其代碼。	The “ in-house” name and/or code of material (if different from 5.29.1);

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5.34.3	收貨日期。	Date of receipt, date and signature of the receiving staff
5.34.4	供應商及原料製造者之名稱。	Supplier’s name and manufacturer’s name;
5.34.5	原料製造者所標示之批號或代號。	Manufacturer’s batch or reference number;
5.34.6	收貨總量及其容器數量。	Total quantity and number of containers received;
5.34.7	入庫後的批號。	The batch number assigned after receipt;
5.34.8	其他如容器狀態。	The batch number assigned after receipt;
5.35	應有程序書敘明原料及包材等入庫後的內部標示、隔離、儲存方式。	There shall be written procedures for the internal labelling, quarantine and storage of starting materials, packaging materials and other materials, as appropriate.
5.36	每一個設備或儀器應有標準作業程序，並放置在設備或儀器附近。	Standard operating procedures shall be available for the operation of each equipment and placed in close proximity to the instrument or equipment.
5.37	應有取樣標準作業程序，敘明權責人員及取樣方式。	There shall be standard operating procedures for sampling, which specify the person(s) authorised to take samples, sampling tools and the sampling instructions.
5.38	應有標準作業程序，敘明半成品、最終半成品或成品之批號訂定方式，確保批號不會重複。批號制定標準作業程序應確保相同的批號不會被使用，重工的產品亦同。	There shall be a standard operating procedure describing the details of the batch / lot numbering system, with the objective of ensuring that each batch of intermediate, bulk, or finished product is identified with a specific batch number. The batch numbering procedures shall assure that the same batch numbers will not be repeatedly used; this applies also to reprocessing.
5.39	批號重置應立即紀錄，包括：重置日期、產品確認及批量。	Batch number allocation shall be immediately recorded, e.g. in a logbook. The record shall include date of allocation, product identity, and size of batch.
5.40	批號標準作業程序應能應用於生產階段及其包裝，且彼此相互關聯。	The standard operating procedures for batch numbering that are applied to the processing stage and to the respective packaging stage shall be related to each other.
5.41	應有程序書作為原料及產品放行或拒收的依據，特別是成品銷售的放行，應由權責人員執行。	Written procedure for quarantine, release and rejection shall be available for materials and products, and in particular for the release for sale of the finished product by the authorised person.
5.42	每批產品的銷售紀錄應留存，以備回收該批產品之需。	Records shall be maintained of the distribution of each batch of a product in order to facilitate the recall of the batch if necessary.
5.43	應有標準作業程序及所採取措施的相關紀錄包括：	Standard operating procedures and associated records of actions taken or, where appropriate, conclusions reached shall be available for:
5.43.1	設備組裝。	equipment assembly;

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5.43.2	檢驗儀器的操作和校準。	operation of analytical apparatus and calibration;
5.43.3	廠房與設備的清潔與維護衛生。	maintenance, cleaning, and sanitisation of equipment and premises;
5.43.4	人員的資格與 GMP 訓練及其衛生。	personnel matters including qualification, GMP training, clothing, and hygiene;
5.43.5	環境監控。	environmental monitoring;
5.43.6	病媒防治。	pest control;
5.43.7	產品不良反應相關之抱怨與產品回收。	adverse product reactions, complaints and product recalls
5.43.8	退回產品或原料。	returns and recovered products, rejected products/materials;
5.43.9	退回產品或原料的處置。	disposal and destruction of the rejected products/materials;
5.43.10	自主檢查或品質稽核。	self-inspection / quality audit
5.44	生產紀錄應放置在重要設備附近，並紀錄校正、維護、清潔、修理等作業，包含日期和負責操作之人員。	Logbooks shall be kept for major or critical equipment and shall record, as appropriate, any calibrations, maintenance, cleaning, or repair operations, including dates and the identity of the people who carried these operations out.
5.45	生產日誌應按時間順序以年月日紀錄產品生產時所使用的設備與區域。	Logbooks shall be recorded in chronological order for the use of all equipment and the areas where the products have been processed.
5.46	上述之規格、程序書及紀錄可合併為一份文件。	Several of the above-mentioned procedures, specifications and/or records may be combined together in one specific document.
第六章	**製造作業**	**CHAPTER 6 – PRODUCTION**
一般原則		**PRINCIPLE**
	應透過適當的廠房與設備，以適當的生產流程製造符合規格的產品，並具備製造作業程序書以確保生產、品質管制及相關人員可據以執行所需要之作業。	With the premises and equipment provided, the processes used in production shall be capable of yielding finished products which conform to their specifications. Defined manufacturing procedures are necessary to ensure that production, quality control and other relevant personnel are instructed on the details of the processes concerned.
一般要求		**GENERAL**
6.1	製造作業應由勝任者進行並監督。	Production shall be performed and supervised by competent people.
6.2	所有原料及產品的操作如收貨、待驗、取樣、儲存、標示、運輸、加工、包裝、配送等均應依書面程序及作業標準執行，必要時予以紀錄。	All handling of materials and products, such as receipt and quarantine, sampling, storage, labelling, dispensing, processing, packaging and distribution shall be done in accordance with written procedures or instructions and, where necessary, recorded.
6.3	所有原料均應經查檢以確保符	All incoming materials shall be checked to ensure

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	合訂購之規格，其容器必要時應清潔，並依規定加以標示。	that the consignment corresponds to the order. Containers shall be cleaned where necessary and labelled with the prescribed data.
6.4	因容器受損或其他原因而影響原料品質者應進行調查、紀錄，並向品管部門報告。	Damage to containers and any other problem, which might adversely affect the quality of a material, shall be investigated, recorded and reported to the Quality Control Department.
6.5	原料收貨後及成品製成後應立即進行原料驗收及成品檢驗，待驗品應加以區隔，直到確認可使用或可出貨。	Incoming materials and finished products shall be physically or administratively quarantined immediately after receipt or processing, until they have been released for use or distribution.
6.6	外購半成品或最終半成品應視同原料，於入廠時進行驗收程序。	Intermediate and bulk products purchased as such shall be handled on receipt as though they were starting materials.
6.7	所有原料及包材應儲存於適當環境，並符合先進先出的原則。	All materials and products shall be stored under the appropriate conditions established by the manufacturer and in an orderly fashion to permit batch segregation and stock rotation.
6.8	應依需要進行製程管制，包括：產率及品質，以符合出貨之產品規格。	Checks on yields, and reconciliation of quantities, shall be carried out as necessary to ensure that there are no discrepancies outside acceptable limits.
6.9	不同產品不得於同一製造區域同時或連續生產，除非能證實不會造成摻混或交叉污染。	Operations on different products shall not be carried out simultaneously or consecutively in the same room unless there is no risk of mix-up or cross-contamination.
6.10	製程中的各階段應防止微生物污染。用來降低黴菌、微生物或其他污染的處理方式必須予以紀錄。	At every stage of processing, products and materials shall be protected from microbial and other contamination. Any treatment used to reduce fungal/microbial contamination or other infestation shall be documented.
6.11	原料處理與製程作業中，應防止粉塵產生或擴散。	When working with dry materials and products, special precautions shall be taken to prevent the generation and dissemination of dust.
6.12	製程中各階段之原料、半成品及其容器應清楚標示所對應產品的適用範圍、批號與製造階段。	At all times during processing, all materials, bulk containers, major items of equipment and where appropriate, rooms used shall 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 shall also mention the stage of production.
6.13	廠內所使用之各種標示(如容器、設備、廠房之標示)應以核定之格式標示，並應清楚不含糊。除了文字以外，可使用不同顏色標示，以管理不同階段產品(例如：待驗、合格、拒收、	Labels applied to containers, equipment or premises shall 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, etc.).

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	已清潔等)。	
6.14	在不同製造作業區域運送成品或半成品的管道或設備應加以查檢，以確保製造過程產品傳送之正確性。	Checks shall 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.
6.15	非與保健營養食品製造作業相關之人員，不得進入製造作業區域。	Access to production premises shall be restricted to authorised personnel.
6.16	原料用水及用於最後沖洗設備的用水，應加以處理以減少微生物污染。	Water used as ingredients or for final rinsing of production equipment shall be treated to minimise microbial contamination.
查證		**VERIFICATION**
6.17	應進行查證來鑑別並證明關鍵製程之有效性。特別是影響產品品質的廠房、設備及製程的任何改變均應進行查證。應以風險評估原則來決定查證的程度與範圍。	Verification work that is needed to prove control of critical aspects of particular operations shall be identified and documented. Significant changes to the facilities, equipment, testing and the processes which may affect the quality of the product shall be verified. A risk assessment approach shall be used to determine the scope and extent of verification. Please refer to details in Appendix 2 – Verification.
預防製造作業中的交叉污染		**PREVENTION OF CROSS-CONTAMINATION IN PRODUCTION**
6.18	原料或產品應避免遭受製造過程中可能釋放的粉塵、氣體、蒸氣、設備上的殘留物質或操作人員衣物所引起的交叉污染。	Contamination of a starting material or of a product by another material or product shall 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.
6.19	應建立適當的措施防止交叉污染措施，例如：	Cross-contamination shall be avoided by appropriate technical or organisational measures, for example:
6.19.1	隔離區域製造或以時間區隔，且製造後應進行適當的清潔。	Production in segregated area, or by campaign (separation in time) followed by appropriate cleaning;
6.19.2	提供適當的空氣流向管控。	Providing appropriate air-locks and air extraction;
6.19.3	減少未經處理或處理未完全的空氣再循環或進入製造過程而造成污染。	Minimising the risk of contamination caused by recirculation or re-entry of untreated or insufficiently treated air;
6.19.4	穿著防護服並在防護區域內處理產品，避免交叉污染。	Wearing protective clothing inside areas where products with special risk of cross-contamination are processed;
6.19.5	使用經核准並有效的清潔程序去污，因為設備無效清潔是一	Using the approved cleaning and decontamination procedures of known effectiveness, as ineffective cleaning of equipment is a common source of

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	種常見的交叉污染源。	cross-contamination;
6.19.6	使用封閉系統進行製造。	Using “ closed systems” of production;
6.19.7	檢驗殘留物，並在設備上使用清潔的標籤。	Testing for residues and use of cleaning status labels on equipment.
6.19.8	每當遭受污染時，需重新進行採樣、稱重、混合及製造處理等作業。	Specific provisions for sampling, weighing, mixing and processing operations of crude plants whenever dust is generated.
6.20	防止交叉污染的方式及其效果應根據程序書定期查檢。	Measures to prevent cross-contamination and their effectiveness shall be checked periodically according to set procedures.
原料		**STARTING MATERIALS**
6.21	原料之採購應有具足夠知識的人員參與。	The purchase of starting materials is an important operation which shall involve personnel who have a particular and thorough knowledge of the suppliers.
6.22	應向列於規格中之合格供應商或其生產者採購原料。建議應和供應商討論其規格，以利未來有相關問題時容易討論與解決。原料供應商應被適當審查並作成紀錄。供應商審查程序應包括：建立合格供應商一覽表、成為合格供應商的初次審查及日後的定期審查(含對供應商進行的現場稽核)。	Starting materials shall 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 are 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. The supplier of the materials shall be adequately assessed and the assessment shall be recorded. The supplier assessment programme shall include the establishment of an approved supplier list which may include alternative supplier, initial assessment before placing the supplier on the approved supplier list and periodic assessment thereafter, provision for on-site audit of the supplier premises, etc.
6.23	每批原料到貨時應查檢是否為完整包裝，並核對送貨單與供應商標籤資訊是否相符。	For each delivery, the containers shall be checked for integrity of package and seal and for correspondence between the delivery note and the supplier's labels.
6.24	若任一次到貨之原料屬不同批號，每一批號均應個別進行取樣、檢驗與放行。	If one material delivery is made up of different batches, each batch shall be considered as separate for sampling, testing and release.
6.25	倉儲中的原料應適當標示，包括：	Starting materials in the storage areas shall be appropriately labelled. Labels shall bear at least the following information:
6.25.1	品名及其內部編碼。	The designated name of the product and the internal code reference where applicable

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6.25.2	批號。	A batch number given at receipt
6.25.3	檢驗狀況(隔離、待驗、放行、拒絕等)。	Where appropriate, the status of the contents (e.g. In quarantine, on test, released, rejected)
6.26	應有程序書對每批原料之規格符合性進行確認；最終半成品亦同。	There shall 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 shall be identified.
6.27	原料應在保存期限內，且經品管部門放行後始能使用。	Only starting materials which have been released by the Quality Control Department and which are within their shelf life shall be used.
6.28	原料應由合格且適當的人員依程序書領用，以確保原料正確性。進行後續秤量並使用清潔且適當標示之容器。	Starting materials shall 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.
6.29	原料之領用與秤量均應分別紀錄並覆核。	Each dispensed material and its weight or volume shall be independently checked and the check recorded.
6.30	同批原料應放置於同一區域，並清楚標示。	Materials dispensed for each batch shall be kept together and conspicuously labelled as such.
操作過程：半成品及最終半成品		**PROCESSING OPERATIONS: INTERMEDIATE AND BULK PRODUCTS**
6.31	配方應於生產前經充分評估檢討，以確保生產作業正確順暢，並具再現性。	Before the introduction of a Master Formula it shall be evaluated sufficiently to determine that it is suitable for routine processing operations, and the ability of the process to be reproducible.
6.32	生產人員應遵循經確認、核准的程序執行製造流程的每個步驟。	Production personnel shall follow defined and authorised procedures for every stage of each manufacturing process.
6.33	生產中之異常應予以紀錄，並由製造及品管主管確認之。	Any deviation from defined procedures shall be recorded and agreed upon between the head of Production Department and the head of Quality Control Department.
6.34	任何製造作業開始之前，應確認工作區域及機器設備沒有與該作業無關之任何原料、產品或文件。	Before any manufacturing begins, steps shall be taken to ensure that the work area and equipment are free from any materials, products, or documents, not required for the current operation.
6.35	製造作業中應進行必要的任何製程管制或相關環境管制，並加以紀錄。	Any necessary in-process controls and environmental controls shall be carried out and recorded.
6.36	對製造過程中盛裝原料的容器或所使用的設備進行標示前，應先去除先前的所有標示。	Before applying labels or marks to materials and equipment, all irrelevant labels or marks previously used shall be removed.
6.37	每批生產之產率應紀錄並與理論值比較，若有明顯差異，則	The final yield of each production stage shall be recorded and checked against the theoretical yield range. Any significant deviation from the expected

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	該批產品不得放行，直到完成適當的調查。	yield shall be recorded and investigated.
6.38	原料及最終半成品應建立儲存條件，並加以管制。	Storage of materials and bulk products must be under controlled condition.
包裝材料		**PACKAGING MATERIALS**
6.39	內包材及印刷包材之購買、處理及管制均與原材料一致。	The purchase, handling and control of primary and printed packaging material shall be accorded attention similar to that given to starting materials.
6.40	印刷包材應特別注意儲存於安全處，避免非權責人員取用。零散的印刷包材應存放於個別容器中，以避免誤用或混用。印刷包材之領用僅限於權責人員依核准之文件程序執行。	Particular attention shall be paid to printed materials. They shall be stored in adequately secure condition such as to exclude unauthorised access. Cut labels and other loose printed materials shall be stored and transported in separate closed containers so as to avoid mix-ups. Packaging materials shall be issued for use only by authorised personnel following an approved and documented procedure.
6.41	每批領用之內包材或印刷包材應有適當的特定編號。	Each delivery or batch of printed or primary packaging material shall be given a specific reference number or identification mark.
6.42	過期包材應廢棄並紀錄之。	Outdated or obsolete primary packaging material or printed packaging material shall be destroyed and this disposal recorded.
包裝作業		**PACKAGING OPERATIONS**
6.43	包裝作業應特別注意降低交叉污染及混用的風險，若同時存在兩種以上產品，除非已進行物理的隔離，否則不得進行包裝。	When setting up a programme for the packaging operations, particular attention shall be given to minimising the risk of the cross-contamination, mix-ups or substitutions. Different products shall not be packaged in close proximity unless there is physical segregation.
6.44	包裝前應有查檢表確認設備的清潔及所有不必要之物品、文件均已清除。	Before packaging operations, steps shall 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 shall be performed according to an appropriate checklist.
6.45	作業中的產品名稱及批號應明顯標示於每個包裝區或生產線。	The name and batch number of the product being handled shall be displayed at each packaging station or line.
6.46	所有產品及包材在運送到包裝區時，應確認其數量及品名與包裝說明書所列一致。	All products and packaging materials to be used shall be checked on delivery to the packaging department for quantity, identity and conformity with the Packaging Instructions.
6.47	充填前應確認容器之清潔，應有措施以避免如玻璃碎片及金屬異物混入。	Containers for filling shall be clean before filling. Measures shall be taken to prevent any contaminants such as glass fragments and metal

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		particles.
6.48	產品完成充填或密封包裝後應儘快貼上標籤，若無法立即進行，應有適當作業程序以避免貼錯標籤。	Normally, filling and sealing shall be followed as quickly as possible by labelling. If it is not the case, appropriate procedure shall be applied to ensure that no mix-ups or mislabelling could occur.
6.49	產品噴印批號或有效日期應針對其正確性進行查檢及紀錄，若為人工打印應定時覆核。	The correct performance of any printing operation (for example batch/lot numbers, expiry dates) to be done separately or in the course of the packaging shall be checked and recorded. Attention shall be paid to printing by hand which shall be re-checked at regular intervals.
6.50	若非於生產線上採用黏貼標籤或套印，應特別注意避免誤用，一般採用自動的卷式標籤較佳。	Special care shall 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.
6.51	應查檢以確認標籤黏貼的相關設備操作正常。	Checks shall be made to ensure that any electronic code readers, label counters or similar devices are operating correctly.
6.52	包材上印刷的文字及資訊應清晰不褪色或不可擦拭除去。	Printed and embossed information on packaging materials shall be distinct and resistant to fading or erasing.
6.53	包裝後產品之查檢應包括：	On-line control of the product during packaging shall include at least checking the following:
6.53.1	包裝外觀。	General appearance of the packages;
6.53.2	包裝完整性。	Whether the packages are complete;
6.53.3	包材是否正確使用。	Whether the correct products and packaging materials are used;
6.53.4	打印是否正確。	Whether any over-printing is correct;
6.53.5	線上監控是否正常運作。	Correct functioning of line monitors.
6.54	取樣的產品不得放回生產線。	Samples taken away from the packaging line shall not be returned.
6.55	異常發生後的產品需由權責人員經特別檢查與調查並核准後始能回到製程，其過程必須詳細紀錄。	Products which have been involved in an unusual event shall only be reintroduced into the process after special inspection, investigation and approval by authorised personnel. Detailed record shall be kept of this operation.
6.56	所使用的包材及半成品總量及其生產的產品數量發生異常時，均應完整調查與重新計算後始得放行。	Any significant or unusual discrepancy observed during reconciliation of the amount of bulk product and printed packaging materials and the number of units produced shall be investigated and satisfactorily accounted for before release.
6.57	包裝作業完畢後，應銷毀未使用但已標示批號之包材，並紀錄銷毀情形。未標示之包材，若要返回倉庫，應遵循程序書。	Upon completion of a packaging operation, any unused batch-coded packaging materials shall be destroyed and the destruction recorded. A documented procedure shall be followed if uncoded printed materials are returned to stock.
成品		**FINISHED PRODUCTS**

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6.58	每批成品應隔離檢驗直到確認其符合產品規格後，始得出貨。	Finished products shall be held in quarantine until their final release under conditions established by the manufacturer.
6.59	成品放行前應有相關評估並文件化，詳如第 7 章品質管制相關規定。	The evaluation of finished products and documentation which is necessary before release of product for sale is described in Chapter 7 (Quality Control).
6.60	成品放行後應適當儲存，其條件由工廠訂定之。	After release, finished products shall be stored as usable stock under conditions established by the manufacturer.
拒收、重工及退回品		**REJECTED, RECOVERED AND RETURNED MATERIALS**
6.61	拒收之原料和產品應清楚標示，分開存放於被管制的區域中，並退回予供應商，必要時重新加工或銷毀，但所有處理措施均應經權責人員核准，並紀錄。	Rejected materials and products shall be clearly marked as such and stored separately in restricted areas. They shall either be returned to the suppliers or, where appropriate, reprocessed or destroyed. Whatever action is taken shall be approved and recorded by authorised personnel.
6.62	不合格產品的再加工應是不允許的。只有在最終產品的品質不受影響，符合規格並且在評估所涉及的風險後，如果是按照規定和授權的程序進行的情況下，才允許再加工，並應保留重新處理的紀錄。	The reprocessing of rejected products shall 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 shall be kept of the reprocessing.
6.63	矯正後的批次應經權責人員核可後始得併入合格品中。該矯正措施須依據書面程序評估相關風險，例如保存期限內的任何可能影響，且須紀錄。	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 the defined stage of manufacture shall be authorised beforehand. This recovery shall be carried out in accordance with a defined procedure after evaluation of the risks involved, including any possible effect on shelf life. The recovery shall be recorded.
6.64	由品管主管決定重工品或經矯正的不合格品需增加的成品檢驗項目。	The need for additional testing of any finished product which has been reprocessed, or into which a recovered product has been incorporated, shall be considered by the Quality Control Department.
6.65	從市場返還的退回品，除品質無虞者之外，均應報廢。品質無虞的退回品應經品管部門依相關程序嚴格審查後，才可標示後續的批次進行販賣或回收之。其審查應包括產品特性、所需儲存方式、歷程及狀態。只要有任何對品質的疑慮，即	Products returned from the market and which have left the control of the manufacturer shall be destroyed unless without doubt their quality is satisfactory; they may be considered for re-sale, re-labelling or recovery in 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

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	使化學性重工可能可以恢復功能性成分的營養素或特定成分含量，均不得重新販賣，所採取的任何作業程序均應紀錄。	issued shall all be taken into account in this assessment. Where any doubt arises over the quality of the product, it shall not be considered suitable for re-issue or re-use, although basic chemical reprocessing to recover active ingredient may be possible. Any action taken shall be appropriately recorded.
第七章	**品質管制**	**CHAPTER 7 – QUALITY CONTROL**
一般原則		**PRINCIPLE**
	工廠應具備設計良好之品管系統以確保所生產之產品持續符合所訂定之規格。品質管制不限於實驗室之操作，而必須涵蓋所有與產品品質相關的決策行為，故應有適當且獨立的品管部門。	Every manufacturing establishment shall have a quality control system so designed as to ensure that the product are manufactured in accordance with adequate conditions and procedures and continue to meet the established specifications. Quality control is not confined to laboratory operations, but must involve all decisions which may concern the quality of the product. For this purpose there shall be an appropriate and independent Quality Control Department.
一般要求		**GENERAL**
7.1	品質管制係透過取樣、制定規格、檢驗、組織化、文件化及產品放行的程序，以確保已完成原料及產品所有必要的檢驗，且在未被審查符合品質需求之前，不會被使用或放行。	Quality control is concerned with sampling, specifications, testing, organisation, documentation and release procedures which ensure that the necessary tests are in fact carried out, and that the materials are not released for use, nor products released for sale and supply until their quality has been assessed to be satisfactory.
7.2	QC 部門應有足以進行品管檢驗的空間、設備及人員，進行生產前、中、後所有必要的檢測。	The Quality Control Department shall have a designated area with sufficient and well trained staff to perform any required analysis before, during and after manufacture.
7.3	若 QC 部門無實驗室可執行檢驗，可委託其他實驗室進行。	If the in-house Quality Control Department cannot perform certain specific analysis, the services of accredited/ recognised external laboratory can be used to conduct the tests.
7.4	成品的品質審查應含生產情形、製程中檢驗、生產與包裝紀錄檢討、成品規格之符合性與包裝檢查。	Finished products assessment shall embrace all relevant factors, including production condition, results of in-process testing, a review of manufacturing (including packaging) documentation, compliance with Finished Product Specification and examination of final finished pack.
7.5	品管人員應進入製造作業區域進行取樣與適當之調查。	Quality Control personnel shall have access to production areas for sampling and investigation as appropriate.
7.6	品管人員應具備相關知識以有能力進行天然原料之鑑定檢	Quality Control personnel shall have particular expertise in products in order to be able to carry

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	驗、攙偽、黴菌及夾雜物之辨識。	out identification tests and recognise adulteration, the presence of fungal growth, infestations, and non-uniformity when receiving and checking crude materials.
7.7	原料及成品之鑑別與品質均應查檢或檢驗。	The identity and quality of materials and finished products shall be checked / tested. The presence of individual ingredient in pre-mixes shall be confirmed.
7.8	品管部門應負責建立與執行品管相關程序書、保存原料與產品的參考用標準品，確保原料和包材的標示，監控產品的安定性。所有的作業應依建立的程序書進行，並紀錄。	Besides these principal duties, the Quality Control Department as a whole will also have other duties, such as to establish and implement all quality control procedures, keep the reference samples of materials and products, ensure the correct labelling of containers of materials and products, ensure the monitoring of the stability of the products, etc. All these operations shall be carried out in accordance with written procedures and recorded.
7.9	應根據可以檢測市售產品任何安定性問題的程序，進行連續且適當的成品安定性監測。	The stability of the finished product shall be monitored according to a continuous appropriate programme that will permit the detection of any stability issue associated with the formulation in the marketed package.
取樣		**SAMPLING**
7.10	原料若由個別天然物組成，且具不均勻性，其取樣應由勝任者進行，且每批均應進行鑑別，並紀錄之。	Due to the fact that crude material shall be an aggregate of individual natural materials i.e. contain an element of heterogeneity, the sampling has to be carried out with special care by competent personnel. Each batch shall be identified by its own documentation.
7.11	取樣應依經核准之程序書進行，包含：	The sample taking shall be done in accordance with approved written procedures that describe:
7.11.1	取樣方法。	the method of sampling
7.11.2	使用的設備。	the equipment to be used
7.11.3	取樣量。	the amount of the sample to be taken
7.11.4	分裝之操作說明。	instructions for any required subdivision of the sample
7.11.5	盛裝樣品容器之類型和條件。	the type and condition of the sample container to be used
7.11.6	樣品標示。	the identification of containers sampled
7.11.7	儲存狀態。	the storage conditions
7.11.8	取樣器材清潔與儲存之操作說明。	instructions for the cleaning and the storage of sampling equipment.
7.12	參考樣品應可代表所取樣的那一批原料或成品，亦可以監控製造過程中的關鍵點(例如：在製造前或後進行留樣)。	Reference samples shall 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).

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7.13	樣品容器應標示內容物、批號、取樣日期。	Sample containers shall bear a label indicating the contents, with the batch number, the date of sampling and the containers from which samples have been drawn.
7.14	產品的留樣應保存到有效日期後 1 年，且應存於包裝上建議的環境。起始原料(非指溶劑、氣體或水)在容許的情形下應留樣至產品出貨後 2 年，但若其原料之安定性較低，其留樣時間可以縮短。留存樣品的數量應足以作完一次全部檢查的檢驗。	Reference samples from each batch of finished products shall be retained till one year after the expiry date. Finished products shall usually be kept in their final packaging and stored under the recommended conditions. Samples of starting materials (other than solvents, gases and water) shall be retained for at least two years after the release of the product if their stability allows. This period may be shortened if their stability, as mentioned in the relevant specification, is shorter. Reference samples of materials and products shall be of a size sufficient to permit at least a full re-examination.
檢驗		**TESTING**
7.15	應依登錄的產品之劑量與有效物質進行檢驗，其檢驗方法應為國際公認檢驗方法或其他經驗效之檢驗方法。	All testing operations described in the marketing authorization shall be carried out according to approved methods which shall be internationally accepted (Refer to Appendix 1: List of Internationally Accepted References for Test Methods) or other validated test methods.
7.16	檢驗結果應紀錄並查證，以確保一致性，任何計算都應小心審核。	The results obtained shall be recorded and verified to make sure that they are consistent with each other. Any calculations shall be critically examined.
7.17	檢驗過程應予以紀錄，包括：	The test performed shall be recorded and the records shall include at least the following data:
7.17.1	品名(原材料、產品，含適用劑型)。	Name of the material or product and, where applicable, dosage form
7.17.2	批號(原料應含供應商)。	Batch number and, where appropriate, the manufacturers and/or supplier
7.17.3	規格與檢驗方法。	References to the relevant specifications and testing procedures
7.17.4	檢驗結果(含觀察與計算)。	Test results, including observations and calculations, and reference to any certificates of analysis
7.17.5	檢驗日期。	Dates of testing, the name of the analyst and the name of the external laboratory, if applicable
7.17.6	檢驗人員。	Date and signature of the persons who performed the testing
7.17.7	檢驗結果查證人員或委外檢驗之實驗室與日期。	Date and signature of the persons who verified the testing and the calculations, where appropriate
7.17.8	放行或禁止出貨的明確指令及其負責人員。	A clear statement of release or rejection (or other status decision) and the dated signature of the designated responsible person
7.18	生產人員執行的製程管制應依	All the in-process controls, including those made in

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	QC 核准之方式進行並紀錄之。	the production area by production personnel, shall be performed according to methods approved by Quality Control and the results recorded.
7.19	實驗室所使用之藥劑、定量玻璃器皿、溶液調配、標準品及培養基均應管制，依程序書製備與管理並紀錄之。	Special attention shall be given to the quality of laboratory reagents, volumetric glassware and solutions, reference standards and culture media. They shall be prepared in accordance with written procedures and recorded.
7.20	配製備用之藥劑應註明配置日期並簽名。培養基及不穩定之藥劑應註明有效期限及其儲存條件；滴定溶液所需之最後標定日期與其矯正係數亦應註明。	Laboratory reagents intended for prolonged use shall be marked with the preparation date and the signature of the person who prepared them. The expiry date of unstable reagents and culture media shall 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 shall be indicated.
7.21	特定與產品品質有關之檢驗數據(如檢驗結果、產量、或環境控制)，建議針對其趨勢加以分析評估。	For some kinds of data (e.g. analytical test results, yields, environmental controls) it is recommended that records in a manner permitting trend evaluation be kept.
7.22	除了批次檢驗的紀錄外，原始檢驗數據及實驗紀錄簿應留存以利查閱。	In addition to the information which is part of the batch record, other original data such as laboratory notebooks and/or reports shall be retained and readily available.
持續安定性試驗		**ON GOING STABILITY PROGRAMME**
7.23	應建立持續安定性試驗計畫，以監督產品的安定性，並確保其有效成分含量與標示相符。	After marketing, the stability of the product shall be monitored according to a continuous appropriate programme that will permit the detection of any stability issue associated with the formulation in the marketed package.
7.24	持續安定性試驗計畫之目的係監督產品在該適當存放條件下，在有效日期內能符合產品規格。	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.
7.25	除了市售包裝成品外，最終半成品的安定性也應被涵蓋於上述持續安定性試驗計畫中，例如：長時間儲存或從製造者運送至包裝廠的最終半成品，以及長時間儲存之半成品，其安定性均應被評估。若重組產品的安定性評估已涵蓋於製程管制過程中，除非必要，否則不需於本計畫中進行評估。	This mainly applies to the product in the package in which it is marketed / sold, but consideration shall 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 shall be evaluated and studied under ambient conditions. In addition, consideration shall be given to intermediates that are stored and used over prolonged periods. Stability studies on reconstituted product are performed during product development and need

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		not be monitored on an on-going basis. However, when relevant, the stability of reconstituted product can also be monitored.
7.26	本計畫應以書面規範及報告方式呈現，所使用之相關設備應合格並適當維護。	The on-going stability programme shall be described in a written protocol and results formalised as a report. The equipment used for the on-going stability programme (stability chambers among others) shall be qualified and appropriately maintained.
7.27	本計畫應延伸至產品有效期限，應包括，但不限以下參數：	The protocol for an on-going stability programme shall extend to the end of the shelf life period and shall include, but not be limited to, the following parameters:
7.27.1	所需之批次及數量。	Number of batch(es) per strength and different batch sizes, where applicable
7.27.2	相關的物理、化學、微生物與生物檢驗方法及其安定性指標成分。	Relevant physical, chemical, microbiological and biological test methods, stability indicating parameters, where applicable
7.27.3	管制界限。	Acceptance criteria
7.27.4	參考之檢驗方法。	Reference to test methods
7.27.5	產品密封情形。	Description of the container closure system(s)
7.27.6	檢驗頻率。	Testing intervals (time points)
7.27.7	樣品儲存條件。	Description of the conditions of storage
7.27.8	其他產品相關特定條件。	Other applicable parameters specific to the finished product
7.28	本計畫與上市前送交權責機關的長期安定性監測計畫不同。	The protocol for the on-going stability program can be different from that of the initial long-term stability study as submitted in the marketing authorization dossier provided that this is justified and documented in the protocol.
7.29	檢驗的批次數和頻率應足夠進行趨勢分析，每種包裝型態至少一批，且每年進行一次；若以矩陣或交叉設計試驗頻率者，應有科學依據。	The number of batches and frequency of testing shall 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, shall be included in the stability program (unless none are produced during that year). Scientific justification has to be provided in the event that the principle of bracketing and matrixing designs is applied.
7.30	因製造或包裝過程的重大缺失所導致之改變，其所生產之產品，以及重工後的產品亦應列入本監測計畫中。	In certain situations, additional batches shall be included in the on-going stability program. For example, an on-going stability study shall be conducted after any significant change or significant deviation to the process or package. Any reworking, reprocessing or recovery operation shall also be considered for inclusion.

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7.31	本監測計畫報告應使工廠權責人員隨時取得，若本監測計畫由非製造或包裝者進行，則雙方應簽訂同意書，並使製造者隨時可以檢討以符合主管機關之要求。	Results of on-going stability studies shall 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 shall be a written agreement between the parties concerned. Results of on-going stability studies shall be available at the site of manufacture for review by the competent authority.
7.32	本監測過程中若有超出規格或有不尋常之趨勢應進行調查，並進行確認且呈報相關主管機關。有可能遭致影響且於市面流通的該批產品應依本 GMP 規範第 9 章顧客抱怨與產品回收及主管機關之規定處理。	Out of specification or significant atypical trends shall be investigated. Any confirmed out of specification result, or significant negative trend, shall be reported to the relevant competent authorities. The possible impact on batches on the market shall be considered in accordance with Chapter 9 – Complaints and Product Recalls of this GMP Guide and in consultation with the relevant competent authorities.
7.33	本計畫之所有數據摘要及結論應作成書面報告並妥善保管，並應定期檢討。	A summary of all the data generated, including any interim conclusions on the programme, shall be written and maintained. This summary shall be subjected to periodic review.
7.34	有關安定性試驗評估之必要條件，可參閱主管機關公告之健康食品安定性試驗指引。	For stability study requirements, reference shall be made to the Guidelines on Stability Study of Health Food be announced by NRA.
第八章	**委託製造與檢驗**	**CHAPTER 8 – CONTRACT MANUFACTURE AND ANALYSIS**
一般原則		**PRINCIPLE**
	委託製造應有書面合約，以避免造成可能的誤解或品質不符合。 委託者與受託者之間的協議，應明確規範雙方職責。 合約包括任何提議的所有安排，技術或其他安排的變化應按照產品的內容要求。 製造、銷售紀錄和參考樣品應提供給委託者。	Contract manufacture and analysis must be correctly defined, agreed and controlled in order to avoid misunderstandings which could result in a product or work of unsatisfactory quality. There must be a written contract between the Contract Giver and the Contract Acceptor which clearly establishes the duties and responsibilities of each party. The contract must clearly state the way in which the authorized person releasing each batch of product for sale exercises his full responsibility.
委託製造		**CONTRACT MANUFACTURE**
8.1	若有委託製造之情形，應訂定委託者與受託者的書面合約，明確規範雙方權利與責任。有關受委託製造的各種安排，包括任何可能的技術性改變應依產品需求進行，並符合主管機關之要求。	Contract manufacture shall have a written contract agreement between the contract giver and the Contract Acceptor, which clearly establishes the duties and responsibilities of each party. All arrangements for contract manufacture, including any proposed changes in technical or other arrangements, shall be in accordance with the NRA requirements for the product concerned.

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委託檢驗		**CONTRACT ANALYSIS**
8.2	檢驗合約應正確定義，避免可能導致的誤解，需有書面合約協議規範委託者與受託者，確認兩方之職責，合約需載明授權人的權責，例如受託者的化學檢驗人員的責任。	Contract analysis must have a written contract agreement between the contract giver and the Contract Acceptor which clearly establishes the duties and responsibilities of each party.
8.3	有關受委託檢驗的各種安排，包括任何可能的技術性改變，應依產品需求進行，並符合主管機關之要求。	All arrangements for contract analysis, including any proposed changes in technical or other arrangements, shall be in accordance with NRA's requirements for the product concerned.
委託者		**THE CONTRACT GIVER**
8.4	委託者應負責審查受託者的能力，以確保 GMP 要求被遵守。	The Contract Giver shall be responsible for assessing the competency of the Contract Acceptor in successfully carrying out the work/test required and for ensuring by means of the contract that the principles of GMP described in these guidelines are followed.
8.5	委託者應提供受託者所有必要的訊息，以正確進行相關作業。受託者應確保合約接受與充分了解任何與產品或可能造成與工作相關之問題，包括：廠房、設備、人員、其他材料或產品的危害。	The Contract Giver shall provide the Contract Acceptor with all the information necessary to carry out the contracted operations correctly in accordance with the NRA requirements. The Contract Giver shall ensure that the Contract Acceptor is fully aware of any problems associated with the product or the work which might pose a hazard to his premises, equipment, personnel, other materials or other products.
8.6	委託者應確保受託者之產品和原料符合其規格。	The Contract Giver shall ensure that all products and materials delivered by the Contract Acceptor comply with their specifications.
受託者		**THE CONTRACT ACCEPTOR**
8.7	該受託者應有足夠之作業場所、設備、知識和經驗及有能力的人員以完成令委託者滿意的工作。被委託製造者應具備主管機關核發之所需合法證照。	The Contract Acceptor has adequate premises, equipment, knowledge and experience, and competent personnel to carry out satisfactorily the work ordered by the Contract Giver. Contract manufacture shall be undertaken only by a manufacturer who is the holder of a manufacturing authorization issued by the NRA.
8.8	受託者應確保所有的產品或原料進廠時是符合預期的用途。	The Contract Acceptor shall ensure that all products or materials received are suitable for their intended purpose.
8.9	未應經委託者的評估、批准的安排，受託者不可在沒有委託者沒有事先與第三方簽訂合約的狀況下，交付第三方工作。受託者與任何的第三方之間應保證、製造和分析信息是與原	The Contract Acceptor shall not pass to a third party any of the work entrusted to him under the contract without the Contract Giver's prior evaluation and approval of the arrangements. Arrangements made between the Contract Acceptor and any third party shall ensure that the manufacturing and the analytical information is

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	始委託者間同樣的方式。	made available in the same way as between the original Contract Giver and Contract Acceptor.
8.10	受託者應避免任何可能的作業對產品品質或檢驗造成不利的影響。	The Contract Acceptor shall refrain from any activity that may adversely affect the quality of the product manufactured/tested for the contract giver.
合約		**THE CONTRACT**
8.11	委託者和受託者間應制定合約，規定各自與產品的製造和控制有關的責任。合約的技術方面應由具備保健營養食品製造、檢驗和優良製造作業規範知識的合格人員制定。所有製造和檢驗安排必須符合主管機關要求，並經雙方同意。	A contract shall be drawn up between the Contract Giver and the Contract Acceptor which specifies their respective responsibilities relating to the manufacture and the control of the product. Technical aspects of the contract shall be drawn up by competent persons suitably knowledgeable in health supplements manufacturing, analysis and Good Manufacturing Practice. All arrangement for manufacture and analysis must be in accordance with the NRA requirement and agreed by both parties.
8.12	合約應規定品質管制部門負責人發布批次銷售的方式，確保每批產品的生產和檢驗符合國家主管機關的要求。	The contract shall specify the way in which the head of Quality Control Department releasing the batch for sale ensures that each batch has been manufactured and checked for compliance with the requirements of the NRAs.
8.13	合約應明確說明在生產與品質管制過程中，原料採購、檢驗和放行之權責。包括取樣與檢驗之責任，並應註明取樣作業應在製造商的作業區域進行。	The contract shall describe clearly who is responsible for purchasing materials, testing and releasing materials, undertaking production and quality controls, including in-process controls, and who has responsibility for sampling and analysis. In case of contract analysis, the contract shall state whether or not the Contract Acceptor shall take samples at the premises of the manufacturer.
8.14	所有製造、檢驗及配送之紀錄和參考樣品，應可提供給委託者並保存，客訴抱怨或產品瑕疵的產品品質審查紀錄必須在被委託者的相關程序中提及並提供給委託者。	Manufacturing, analytical and distribution records, and reference samples shall be kept by, or be available to, the Contract Giver. Any records relevant to assessing the quality of a product in the event of complaints or a suspected defect must be accessible and specified in the defect / recall procedures of the Contract Giver.
8.15	合約內容應允許委託者查訪受託者之設施。	The contract shall permit the Contract Giver to visit the facilities of the Contract Acceptor.
8.16	在委託檢驗的情況下，受託者仍應接受主管機關的檢查。	In the case of contract analysis, the Contract Acceptor shall understand that he is subject to inspection by the competent Authorities.
第九章	**客訴和產品回收**	**CHAPTER 9 – COMPLAINTS AND PRODUCT RECALLS**
一般原則		**PRINCIPLE**
	所有客訴或潛在的產品缺失必須留存紀錄，依相關程序進行	All complaints and other information concerning potentially defective products must be kept and reviewed according to written procedures. In order

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	檢討，並建立回收系統，必要時，可迅速、有效地從市面上回收有瑕疵之產品。	to provide for all contingencies, a system shall be designed to recall, if necessary, promptly and effectively products known or suspected to be defective from the market.
產品的客訴		**PRODUCT COMPLAINTS**
9.1	申訴通常與產品品質有關，包括其物理特性或包裝狀態。可由消費者、經銷商或主管機關，以口頭或書面方式向製造商提出申訴。	Product complaints are usually concerned with the quality of the product such as its physical properties, or condition of its packaging. Complaints (internal or external) could be made to the manufacturer, verbally or in writing by consumers, distributors or the NRA.
9.2	應對所有申訴進行調查或評估。應制定所有書面或口頭投訴之處理程序。由品質管理部門檢討書面紀錄，並留存書面紀錄。	All complaints shall be investigated and evaluated. Written procedures describing the handling of all written and verbal complaints regarding the product shall be established and followed. Such procedures shall include provisions for review by the Quality Control unit. A written record of each complaint shall be maintained in a file designated for product complaints.
9.3	應有專門人員負責處理投訴，並有相關措施及有適當人員協助處理。	A person shall be designated responsible for handling the complaints.
9.4	採取的矯正行動應有書面程序，若是有關可能的產品缺陷時，必要時，應考慮回收作業。	There shall 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.
9.5	有關產品缺陷的投訴應紀錄細節與徹底的調查，應有負責品質管制的人進行這些問題的研究。	Any complaint concerning a product defect shall be recorded with all the original details and thoroughly investigated. The person responsible for Quality Control shall be part of the team.
9.6	應考慮投訴是否有作假嫌疑。	Special attention shall be given in establishing whether the product which is the subject of a complaint, genuine or is a counterfeit product.
9.7	如果發現可能是批次問題造成產品缺陷，則應考慮查檢其他批次，以確定是否也受到影響，若其他批次也出現產品缺陷，應進行調查。	If a product defect is discovered or suspected in a batch, consideration shall be given to check other batches in order to determine whether they are also affected. In particular, other batches which may contain reworks of the defective batch shall be investigated.
9.8	申訴結果的決定和處理作業應紀錄，並參考對應的批次紀錄。	All decisions and measures taken as a result of a complaint shall be recorded and referenced to the corresponding batch records.
9.9	申訴紀錄應定期進行檢討，須注意是特定或是反覆出現的問題。	Complaint records shall be reviewed regularly for any indication of specific or recurring problems requiring attention and possibly the recall of marketed products.
9.10	對於經常發生的問題，應針對其趨勢進行分析，以找出可能	For recurring problem, a trending shall be established in order to identify the possible

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	的系統性失誤。	systemic defects.
9.11	製造商針對製造過程、產品的缺失或嚴重品質問題進行改善措施，應主動通知主管機關。	The NRA shall be informed if a manufacturer is considering action following possibly faulty manufacture, product deterioration, or any other serious quality problems with a product.
9.12	應向主管機關及投訴者提供改善處理重點摘要。	The NRA and the complainant shall be furnished with a summary of the action taken.
產品回收		**PRODUCT RECALLS**
9.13	製造商應制定成品回收責任與程序，以便從供應鏈的任何一個環節進行回收作業。	Responsibility and procedures for recall of the product shall be established by the manufacturer to facilitate the recall of a batch from any link of the distribution chain when this becomes necessary.
9.14	產品回收的程度及其所依據的程序應依主管機關規定進行。	The recall procedures shall take into account the degree and level of recall which in line with the NRA requirement.
9.15	採取任何回收有嫌疑或是已知有缺陷或是危險產品的行動，應遵循標準化程序迅速地按照既定的計畫執行。	Any action taken to recall a product suspected or known to be defective or hazardous, shall be done immediately and in accordance with a pre-determined plan. The procedures to be followed shall be specified in writing and made known to all that may be concerned.
9.16	應有負責人執行和負責協調回收作業，處理回收作業具有適當的程度與急迫性，一般為獨立於銷售及營銷部門之外。	A person shall be designated as responsible for execution and co-ordination of recalls and shall be supported by sufficient staff to handle all the aspects of the recalls with the appropriate degree of urgency. This responsible person shall normally be independent of the sales and NRA requirements.
9.17	應建立書面程序，定期查檢，必要時，予以更新。	There shall be established written procedures, regularly checked and updated when necessary, in order to organise any recall activity.
9.18	回收操作應及時被推動。	Recall operation shall be capable of being initiated immediately and at any time.
9.19	若產品被懷疑有缺陷需回收時，應立即通知可能已運銷該產品的各國主管機關。	All NRA of all countries to which products may have been distributed shall be informed immediately if products are intended to be recalled because they are, or are suspected of being defective.
9.20	販售紀錄可隨時提供負責回收的人員，並應包括足夠的訊息，包括批發商和直接提供的客戶(地址、電話、傳真、工作時間、批次等)，包括出口的產品。	The distribution records shall be readily available to the person(s) responsible for recalls, and shall contain sufficient information on distributor / importer / retailer / wholesalers and directly supplied customers (with latest and valid addresses, contact number including mobile phone, phone and/or fax numbers inside and outside working hours, batches and amounts delivered), including those for exported products.
9.21	回收的產品應查明並安全分開	Recalled products shall be identified, recorded and stored separately in a secure area while awaiting a

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	存放，在等待區等待最後決定。	decision on their fate.
9.22	回收過程的發展應紀錄和最終報告，包括過程中的數量。	The progress of the recall process shall be recorded and a final report issued, including reconciliation between the delivered and recovered quantities of the products.
9.23	應定期評估回收的有效性。	The effectiveness of the arrangements for recalls shall be evaluated regularly.
產品不良反應之客訴		**COMPLAINTS ON ADVERSE PRODUCT REACTIONS**
9.24	應徹底調查並紀錄保健營養食品的不良反應，嚴重的不良反應應立即通報主管機關。	Unexpected adverse product reactions resulting from the use of the product must be thoroughly investigated and documented. Reports of serious unexpected adverse reactions shall be immediately forwarded to the NRA.
第十章	**自我檢查**	**CHAPTER 10 – SELF-INSPECTION**
一般原則		**PRINCIPLE**
	透過自主檢查(例如內部稽核)來定期監督工廠是否符合 GMP 規範，並找出其品保系統之缺失以進行改善。	Self-inspections shall be conducted in order to monitor the implementation and compliance with Good Manufacturing Practice principles and to propose necessary corrective measures.
10.1	有關人員、廠房、設備、文件、生產、品管、產品配送、客訴及產品回收處理及內部稽核，均應依預定計畫定期加以查核，以查證其符合品質保證的原則。	Personnel matters, premises, equipment, documentation, production, quality control, distribution of the products, arrangements for dealing with complaints and recalls, and self-inspection, shall be examined at intervals following a pre-arranged program in order to verify their conformity with the principles of Quality Assurance.
10.2	自主檢查應獨立進行，必要時，可邀請外部專家參與。	Self-inspection shall be conducted in an independent and detailed way by designated competent person(s) from the company. The independent audits by external experts may also be useful.
10.3	自主檢查應有紀錄，包括所有觀察事項及矯正措施計畫，後續之改善措施亦應紀錄。	All self-inspections shall be recorded. Reports shall contain all the observations made during the inspections and, where applicable, proposals for corrective actions and preventive actions, and corresponding time frames. Statements on the actions subsequently taken shall also be recorded.

(依在保健營養食品 GMP 指引中首次出處排序)

詞彙表	Glossary	首次出處
原料	Starting materials	1.2.4
包材	Packaging materials	1.2.4
半成品	Intermediate products	1.2.5
成品	Finished products	1.2.6
有效日期	Shelf life / Expiration date	1.2.8 / 2.3.8
檢查	Inspection	1.2.9
評鑑	Appraise	1.2.9
檢討	Review	1.3.1
查證	Verify	1.3.2
核准	Approve	1.3.3.5
調查	Investigation	1.3.6
查核	Examine	1.3.10
檢驗	Test / Analytical	1.4 / 5.13.3
最終半成品	Bulk products	1.4.1
監控	Monitor	1.4.1
審查	Assess	1.4.6
評估	Evaluate	1.4.6
查檢	Check	2.2.4