# 優良實驗室操作原則
# -國際間相互採認檢驗數據的共識

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## 前　　言

優良實驗操作(Good Laboratory Practices，以下簡稱GLP)是一種管理概念，在進行非臨床人體健康及環境安全研究(Non-Clinical Health and Environmental Safety Study)過程中，有關其計畫、執行、監督、記錄、歸檔、與報告等行政組織運作的過程和實施條件之優質系統。世界許多先進國家對於醫藥、農藥、食品與飼料添加物、化粧品、獸藥產品、以及工業化學物質等項目(未來甚至可能推及基因改造作物)，在申請註冊或許可證時，多立有相關法規要求非臨床人體健康及環境安全試驗研究的品質。以申請新有效成份化學農藥登記為例，其在登記註冊時用於評估安全性所必需提繳的毒性測試(如動物毒性、基因毒性、致癌性)、物理化學性狀檢驗(如農藥規格檢驗)、殘留量檢驗、環境毒理試驗(如魚毒、鳥毒、生物分解與累積)、田間藥效試驗、或藥害試驗等相關研究，都包括在此範圍內。

1976 年，美國食品藥物管理局(Food and Drug Administration, FDA)最早提出 GLP 規範(1979 年聯邦第 21 CFR Part 58 法案正式生效)，嚴格規定廠商應對其產製的醫藥、動物用藥、醫療器材、食品添加物等的安全性和有效性負責，並授權政府相關部門負責稽核廠商的測試結果，只有經過這些機構認可核准後方可上市。其後，美國對於環境保護(EPA 1980)、毒物管理(TSCA 1989)、和殺蟲、殺菌與殺鼠藥 (FIFRA 1989)等管理也都立法要求實施GLP原則。而日本、英國(1982)；法國、德國(1983)；瑞典、西班牙(1985)；荷蘭、義大利、韓國(1986)；比利時、瑞士(1988)等國家也相繼立法推行GLP 實驗制度。我國衛生署亦於2000 年公告「藥品非臨床試驗安全性規範」要求實施GLP，農業委員會則於2004 年公告「農藥登記之毒理資料試驗準則」，要求農藥毒理試驗應依中央主管機關公告之GLP 規範或參照OECD、美國EPA 的GLP 規範為之。中國則早我一年頒布「藥品非臨床研究質量管理規

行政院農業委員會農業藥物毒物試驗所技術專刊第 140 號。

範」推行 GLP。由於各國因其國情與管理對象領域(如農藥、醫藥、獸藥、食品添加、環衛...等)的差異，各國及其主管機關之法規訂定的 GLP 規範，則未盡相同。世界各國之主管機關彼此之間也可藉此「數據品質」標準之差異，而技巧性地作為保護其國內產業之貿易技術障礙。

## 國際間相互採認檢驗數據的機制

由於「數據品質標準」的議題有其國際性的重要性，如果各國主管機關可以信賴國外所開發的安全檢驗數據，則政府與工業界可避免重複性的檢驗而節省經費與資源。而且，除了有助於共同維護人體健康與保護環境之外，國際間遵循共同的 GLP 準則，還可促進資訊的交換與避免在貿易時非關稅性障礙的出現。像在歐洲共同體成員國之間進行化學品貿易時，就以簽署「諒解備忘錄(Memoranda of Understanding, MOU)」達成雙邊協議：經某一會員國的 GLP 管理機構核准的數據，將被其它會員國的 GLP 管理機構所接受。而世界經濟合作開發組織(Organization for Economic Cooperation and Development, OECD)則以更開闊的胸襟，來推行這種國際間相互採認檢驗數據機制的精神。

1978 年，OECD 以美國 FDA 的 GLP 準則為藍本，研擬 OECD GLP 準則，於 1981 年正式公告，作為其會員國及國際組織之間，相互採認試驗數據的協議(Mutual Acceptance of Data, MAD)，以促進其會員國之間的經濟合作利益。OECD 理事會在 1997 年，更將 GLP MAD 開放給非會員國申請，凡簽署加入 OECD GLP MAD 之國家或組織，其國內之檢驗研究依 OECD GLP 原則執行與稽核監督的試驗報告，應被其它國家認可接受，反之亦然。而非會員國在遵行此 OECD 理事會法案時，可具有與會員國相同的權利與義務。更重要的是：加入 OECD GLP MAD 可以用區域(如香港)、機構(如美國的 FDA 與 EPA)、國家(如紐西蘭)或國際組織(如歐洲共同體)為單位，個別向 OECD 理事會提出申請。

目前已加入 OECD GLP MAD 協定的國家包括 26 個 OECD 會員國和剛通過的中國(非會員國)。印度、巴西、俄羅斯正以觀察員身份被審核中，而比利時、盧森堡、新加坡、印尼、香港和臺灣也開始提出申請。由於世界衛生組織(World Health Organisation, WHO)、國際標準組織(International Organisation for Standardisation, ISO)、歐盟執行委員會(Commission of European Communities)等國際組織也都屬於 OECD 的會員，各國或組織機構

透過加入OECD GLP MAD 的機制，其執行監督稽核的實驗室之檢驗報告亦可輾轉被世界其它重要的國際組織或國家所接受。同時，各國主管機關對於他國之報告有疑義時，亦可透過此 GLP MAD 機制，請求協助海外稽核它國的監督機構與其檢驗機構的試驗執行狀況。因此，各國之實驗室遵行 OECD GLP 規範，實為其檢驗數據報告被世界大多數國家接受的重要條件之一。

## 世界經濟合作開發組織的優良實驗室操作原則
## (OECD GLP Principle)

OECD 對於化學物質的控管法規是基於一種前瞻性理念—即藉檢驗及評估化學物質以判定其潛在危險而預防風險。因此，要求評估化學物質安全性的檢驗數據必須俱備「高品質、嚴謹、與可重複性」之 GLP 原則。此原則針對試驗研究的計畫、執行、監督、記錄、檔案處理、與報告等行政組織運作過程和實施條件，從檢驗單位組織與人員、品質保證計畫、環境設施、儀器設備材料與試劑、檢驗系統、試驗物質與參考物質、標準操作程序、研究之執行、研究結果之報告、記錄與材料之保存等十項要點詳加規範。以下並列 OECD GLP 原則 1997 年修訂版之原文及譯稿，供讀者瞭解全貌。

# GOOD LABORATORY PRACTICE PRINCIPLES

# 優良實驗操作(GLP)原則

**1. Test Facility Organisation and Personnel** 檢驗機構組織與人員

1.1 Test facility management's responsibilities 檢驗機構負責人之責任

1.1.1 Each test facility management should ensure that these Principles of Good Laboratory Practice are complied with, in its test facility.

每個檢驗機構負責人應確保其機構遵守 GLP 原則。

1.1.2 At a minimum it should：檢驗機構負責人至少應：

(a)ensure that a statement exists which identifies the individual(s) within a test facility who fulfil the responsibilities of management as defined by these Principles of Good Laboratory Practice；

聲明保證有確認檢驗機構內人員依 GLP 原則履行管理的責任；

(b)ensure that a sufficient number of qualified personnel, appropriate facilities, equipment, and materials are available for the timely and proper conduct of the study；

保證有足夠具資格人員、適當的設施、設備與材料，可隨時供試驗適當地執行；

(c)ensure the maintenance of a record of the qualifications, training, experience and job description for each professional and technical individual；

保證維持每位專業技術人員之資格、訓練、經驗、與職務說明之記錄；

(d)ensure that personnel clearly understand the functions they are to perform and, where necessary, provide training for these functions；

保證人員清楚地了解其工作職掌，必要時提供訓練；

(e)ensure that appropriate and technically valid Standard Operating Procedures are established and followed, and approve all original and revised Standard Operating Procedures；

保證建立並遵照技術上有效而適當的標準操作程序書，並核定所有原始與修訂的標準操作程序書；

(f)ensure that there is a Quality Assurance Programme with designated personnel and assure that the quality assurance responsibility is being

performed in accordance with these Principles of Good Laboratory Practice；

保證有指派人員執行品質保證計畫，並保證依照GLP 原則履行品保責任；

(g)ensure that for each study an individual with the appropriate qualifications, training, and experience is designated by the management as the Study Director before the study is initiated. Replacement of a Study Director should be done according to established procedures, and should be documented.

保證每次試驗開始前，由負責人指定一位研究主任，其確具適當的資格、訓練與經驗。研究主任之變更應依已建立的書面程序為之。

(h)ensure, in the event of a multi-site study, that, if needed, a Principal Investigator is designated, who is appropriately trained, qualified and experienced to supervise the delegated phase(s) of the study. Replacement of a Principal Investigator should be done according to established procedures, and should be documented.

保證在多試驗場所進行之試驗，若需要時，指定一位試驗主持人其確經適當訓練、具資格與經驗以監管被委派的試驗部分。試驗主持人之變更應依已建立的書面程序為之。

(i)ensure documented approval of the study plan by the Study Director；

保證試驗計畫經研究主任書面批准；

(j)ensure that the Study Director has made the approved study plan available to the Quality Assurance personnel；

保證研究主任批准的試驗計畫書會給品保人員；

(k)ensure the maintenance of an historical file of all Standard Operating Procedures；保證維持所有標準操作程序之歷史檔案；

(l)ensure that an individual is identified as responsible for the management of the archive(s)；保證指派專人負責檔案管理；

(m)ensure the maintenance of a master schedule；

保證維持主要進度表；

(n)ensure that test facility supplies meet requirements appropriate to their use in a study；保證檢驗機構提供符合試驗用之所需；

(o)ensure for a multi-site study that clear lines of communication exist between the Study Director, Principal Investigator(s), the Quality

Assurance Programme(s) and study personnel；

保證在多試驗場所進行之試驗，研究主任、試驗主持人、品保系統、與研究人員之間有清楚的連絡管道；

(p)ensure that test and reference items are appropriately characterised；

保證試驗物質與參考物質之特性有適當地確認；

(q)establish procedures to ensure that computerized systems are suitable for their intended purpose, and are validated, operated and maintained in accordance with these Principles of Good Laboratory Practice.

建立程序以保證電腦化系統適用於其預定目標、且經驗證、並依 GLP 原則操作與維持。

1.1.3 When a phase(s) of a study is conducted at a test site, test site management (if appointed) will have the responsibilities as defined above with the following exceptions：1.1.2 (g), (i), (j) and (o).

當一試驗的部分在一個試驗場所執行時，試驗場所負責人(若有指定)應負如上述之責任，但 1.1.2. (g), (i), (j) 與 (o) 條款除外。

1.2 *Study director's Responsibilities* 研究主任的責任

1.2.1 The Study Director is the single point of study control and has the responsibility for the overall conduct of the study and for its final report.

研究主任為一試驗控管點，負責總主持試驗及總結報告。

1.2.2 These responsibilities should include, but not be limited to, the following functions. The Study Director should：

研究主任之責任至少應包括下列所述：

(a)approve the study plan and any amendments to the study plan by dated signature；

簽署押日期核准試驗計畫及任何計畫之修訂；

(b)ensure that the Quality Assurance personnel have a copy of the study plan and any amendments in a timely manner and communicate effectively with the Quality Assurance personnel as required during the conduct of the study；

保證在主持試驗時，品保人員能適時獲有一份試驗計畫書及任何修訂版，需要時能有效地與品保人員溝通；

(c)ensure that study plans and amendments and Standard Operating Procedures are available to study personnel；

保證試驗人員可獲得試驗計畫書與修訂版及標準操作程序書；

(d)ensure that the study plan and the final report for a multi-site study

identify and define the role of any Principal Investigator(s) and any test facilities and test sites involved in the conduct of the study ;

保證在多試驗場所進行之試驗的試驗計畫書與總結報告中，有區分及確定參與其主持之試驗的任何試驗主持人、檢驗機構、與試驗場所的角色；

(e)ensure that the procedures specified in the study plan are followed, and assess and document the impact of any deviations from the study plan on the quality and integrity of the study, and take appropriate corrective action if necessary; acknowledge deviations from Standard Operating Procedures during the conduct of the study ;

保證實驗步驟確依試驗計畫進行，並書面評估任何偏離試驗計畫對試驗的品質與完整性之衝擊，必要時採取適當的矯正措施，認可執行試驗時偏離標準操作程序；

(f)ensure that all raw data generated are fully documented and recorded;

保證所有產出之原始資料皆有完整之書面記錄；

(g)ensure that computerised systems used in the study have been validated ;

保證試驗使用之電腦系統皆已驗證過；

(h)sign and date the final report to indicate acceptance of responsibility for the validity of the data and to indicate the extent to which the study complies with these Principles of Good Laboratory Practice ;

在總結報告簽署押日期以承諾對數據的有效性負責，並指出試驗遵循 GLP 原則的程度範圍；

(i)ensure that after completion (including termination) of the study, the study plan, the final report, raw data and supporting material are archived.

保證試驗結束(包括中止)後，試驗計畫書、總結報告、原始資料、與證明材料皆已歸檔。

1.3 *Principal investigator's Responsibilities* 試驗主持人之責任

The Principal Investigator will ensure that the delegated phases of the study are conducted in accordance with the applicable Principles of Good Laboratory Practice.

試驗主持人保證被指派部分的試驗有依適用的 GLP 原則執行。

1.4 *Study Personnel's Responsibilities* 試驗研究人員之責任

1.4.1 All personnel involved in the conduct of the study must be

knowledgeable in those parts of the Principles of Good Laboratory Practice which are applicable to their involvement in the study.

所有參與執行試驗研究人員必須了解其參與試驗部分對應於 GLP 原則的部分。

1.4.2 Study personnel will have access to the study plan and appropriate Standard Operating Procedures applicable to their involvement in the study. It is their responsibility to comply with the instructions given in these documents. Any deviation from these instructions should be documented and communicated directly to the Study Director, and/or if appropriate, the Principal Investigator(s).

試驗研究人員應得接近試驗計畫書及適用於其參與試驗部分的標準操作程序書。其責任為依照這些文件指引操作。任何偏離指引之操作必須記載並直接與研究主任 (及/或試驗主持人) 溝通。

1.4.3 All study personnel are responsible for recording raw data promptly and accurately and in compliance with these Principles of Good Laboratory Practice, and are responsible for the quality of their data.

所有試驗研究人員皆應遵守 GLP 原則，負責其記錄之原始數據為試驗當時之正確記錄，並對其記錄數據之品質負責。

1.4.4 Study personnel should exercise health precautions to minimize risk to themselves and to ensure the integrity of the study. They should communicate to the appropriate person any relevant known health or medical condition in order that they can be excluded from operations that may affect the study.

試驗研究人員應注意保健以減低試驗對其自身的風險，也確保試驗的完整性。任何有關健康或醫療狀況應與適當人員連繫，以便可能影響試驗時，可被取消其操作勞務。

**2. Quality Assurance Programme** 品質保證計畫

2.1 *General* 通則

2.1.1 The test facility should have a documented Quality Assurance Programme to assure that studies performed are in compliance with these Principles of Good Laboratory Practice.

檢驗機構應有書面的品質保證系統以確保試驗之執行遵循 GLP 原則。

2.1.2 The Quality Assurance Programme should be carried out by an individual or by individuals designated by and directly responsible to management and who are familiar with the test procedures.

品質保證系統應由負責人指派人員為之，其直接對負責人負責，且熟悉試驗步驟。

2.1.3 This individual(s) should not be involved in the conduct of the study being assured.

品保人員應不參與其所保證之試驗的執行。

2.2 *Responsibilities of the Quality Assurance Personnel* 品保人員之責任

2.2.1 The responsibilities of the Quality Assurance personnel include, but are not limited to, the following functions. They should：

品保人員之責任至少應包括：

(a)maintain copies of all approved study plans and Standard Operating Procedures in use in the test facility and have access to an up-to-date copy of the master schedule；

保有檢驗機構使用之所有認可的試驗計畫書與標準操作程序書之複本，並能取得最新版的主要進度表；

(b)verify that the study plan contains the information required for compliance with these Principles of Good Laboratory Practice. This verification should be documented；

書面驗證試驗計畫包含遵循 GLP 原則所需之資料；

(c)conduct inspections to determine if all studies are conducted in accordance with these Principles of Good Laboratory Practice. Inspections should also determine that study plans and Standard Operating Procedures have been made available to study personnel and are being followed.

執行稽核以判定是否所有試驗都依從 GLP 原則。稽核亦應含判定試驗研究人員可取得試驗計畫書與標準操作程序書而且確實依照執行。

Inspections can be of three types as specified by Quality Assurance Programme Standard Operating Procedures:

稽核可依品質保證系統之標準作業程序而分 3 種類型：

- Study-based inspections, 依試驗稽核，
- Facility-based inspections, 依設施稽核，
- Process-based inspections. 依操作稽核。

Records of such inspections should be retained.

所有稽核紀錄皆須保存。

(d)inspect the final reports to confirm that the methods, procedures, and

observations are accurately and completely described, and that the reported results accurately and completely reflect the raw data of the studies ;

稽核總結報告以確認試驗之方法、步驟、及觀察皆被完全正確地描述，且結果報告完全正確地反映自試驗之原始數據資料；

(e)promptly report any inspection results in writing to management and to the Study Director, and to the Principal Investigator(s) and the respective management, when applicable ;

任何稽核結果應適時儘快書面報告給負責人、研究主任、試驗主持人、與各別的主管；

(f)prepare and sign a statement, to be included with the final report, which specifies types of inspections and their dates, including the phase(s) of the study inspected, and the dates inspection results were reported to management and the Study Director and Principal Investigator(s), if applicable. This statement would also serve to confirm that the final report reflects the raw data.

製備並簽署一份聲明含在總結報告裡，敘明稽核類型與日期，包括稽核之試驗部分，並將稽核結果日期報告給試驗負責人、研究主任與試驗主持人。此聲明亦將供確認試驗報告反映原始數據用。

**3. Facilities** 環境設施

3.1 *General* 通則

3.1.1 The test facility should be of suitable size, construction and location to meet the requirements of the study and to minimise disturbance that would interfere with the validity of the study.

檢驗機構應有適當空間大小、建築、與場所以供符合試驗所需，並減少可能干擾試驗效力之阻礙。

3.1.2 The design of the test facility should provide an adequate degree of separation of the different activities to assure the proper conduct of each study.

檢驗機構設施之設計應提供足以區隔供不同活動之空間以確保每個試驗可被適當執行。

3.2 *Test system Facilities* 試驗體系之環境設施

3.2.1 The test facility should have a sufficient number of rooms or areas to assure the isolation of test systems and the isolation of individual

projects, involving substances or organisms known to be or suspected of being biohazardous.

檢驗機構應有足夠的房間數或區域，以確保可以區隔試驗體系、個別計畫、相關之物質、或已知或疑具生物危害性之物質或生物體。

3.2.2 Suitable rooms or areas should be available for the diagnosis, treatment and control of diseases, in order to ensure that there is no unacceptable degree of deterioration of test systems.

適當的房間或區域應具有可供疾病診斷、處理與控制疾病之用，以確保試驗體系不會變質為不可容許之程度。

3.2.3 There should be storage rooms or areas as needed for supplies and equipment. Storage rooms or areas should be separated from rooms or areas housing the test systems and should provide adequate protection against infestation, contamination, and/or deterioration.

應有足夠的儲存房間或區域供放試驗物品及儀器設備。儲存房間或區域應與飼養試驗體系之房間或區域區隔，並提供適當防護以免遭感染、污染或變質。

3.3 *Facilities for Handling Test and Reference Items*

處理試驗物質與參考物質之設施

3.3.1 To prevent contamination or mix-ups, there should be separate rooms or areas for receipt and storage of the test and reference items, and mixing of the test items with a vehicle.

為避免污染或混淆，應有區隔的房間或區域以供試驗物質、參考物質、與試驗物質和賦形劑的混合物等之配製與儲存用。

3.3.2 Storage rooms or areas for the test items should be separate from rooms or areas containing the test systems. They should be adequate to preserve identity, concentration, purity, and stability, and ensure safe storage for hazardous substances.

試驗物質的儲存房間或區域應與含試驗體系之房間或區域區隔。其應可資保持識別、濃度、純度與穩定性，並確保危險物品被安全保存。

3.4 *Archive Facilities* 檔案設施

Archive facilities should be provided for the secure storage and retrieval of study plans, raw data, final reports, samples of test items and specimens. Archive design and archive conditions should protect contents from untimely

deterioration.

檔案設施應提供試驗計畫書、原始資料、總結報告、試驗物質之樣品與標本之安全存取。檔案設計與檔案狀況應保護其內容免於日久毀損。

3.5 *Waste Disposal* 廢棄物丟棄

Handling and disposal of wastes should be carried out in such a way as not to jeopardise the integrity of studies. This includes provision for appropriate collection, storage and disposal facilities, and decontamination and transportation procedures.

廢棄物之處理與丟棄方式應不可危及試驗的完整性。此包括提供適當的收集、儲存與丟棄設施、以及去污染及運送程序等。

**4. Apparatus, Material, and Reagents** 儀器設備、材料與試劑

4.1 Apparatus, including validated computerised systems, used for the generation, storage and retrieval of data, and for controlling environmental factors relevant to the study should be suitably located and of appropriate design and adequate capacity.

儀器設備包括已驗證的電腦系統、產生與存取資料用、控制試驗相關環境條件用，應放適當位置並有適當的規劃與足夠的空間容量。

4.2 Apparatus used in a study should be periodically inspected, cleaned, maintained, and calibrated according to Standard Operating Procedures. Records of these activities should be maintained. Calibration should, where appropriate, be traceable to national or international standards of measurement.

試驗用儀器設備應依標準操作程序定期檢查、清潔、保養與校正。這些作業之記錄應予保存。適當的校正應可追溯到國家或國際量測標準。

4.3 Apparatus and materials used in a study should not interfere adversely with the test systems.

試驗用儀器設備與材料不可有害地干擾測試體系。

4.4 Chemicals, reagents, and solutions should be labelled to indicate identity (with concentration if appropriate), expiry date and specific storage instructions. Information concerning source, preparation date and stability should be available. The expiry date may be extended on the basis of documented evaluation or analysis.

化學物質、試劑、與溶液應予標識指示身份證明(必要時附濃度)、有效期限、與特定儲存說明。並具備有關其來源、製備日期與穩定性等資料。有效期限可依評估或分析證明文件予以延長。

**5. Test systems** 測試體系

5.1 *Physical/Chemical* 物理/化學性測試體系

5.1.1 Apparatus used for the generation of physical/chemical data should be suitably located and of appropriate design and adequate capacity.
用於產出物理/化學性資料數據之儀器裝置，應有適合的位置、適當的設計、與足夠的容量。

5.1.2 The integrity of the physical/chemical test systems should be ensured.
物理/化學性測試體系之原本特性應予確定。

5.2 *Biological* 生物性測試體系

5.2.1 Proper conditions should be established and maintained for the storage, housing, handling and care of biological test systems, in order to ensure the quality of the data.
應建立並維持生物測試體系的儲存、房舍、處理、與照護之適當條件，以確保數據資料的品質。

5.2.2 Newly received animal and plant test systems should be isolated until their health status has been evaluated. If any unusual mortality or morbidity occurs, this lot should not be used in studies and, when appropriate, should be humanely destroyed. At the experimental starting date of a study, test systems should be free of any disease or condition that might interfere with the purpose or conduct of the study. Test systems that become diseased or injured during the course of a study should be isolated and treated, if necessary to maintain the integrity of the study. Any diagnosis and treatment of any disease before or during a study should be recorded.
新收到的動、植物測試體系在評估確定其健康狀態前應予隔離。若有任何不正常死亡或罹病發生則整批生物皆不用於試驗，必要時應以人道方式銷毀。從試驗起始日起，測試體系應避免罹病或可能干擾試驗之狀況。若為保持試驗進行之完整性，測試體系於試驗中得病或受傷時應予隔離處理。試驗中任何疾病之診斷與處理皆應記錄。

5.2.3 Records of source, date of arrival, and arrival condition of test systems should be maintained.
測試生物體系之來源、收件日、與收件狀況等記錄應予保存。

5.2.4 Biological test systems should be acclimatised to the test environment for an adequate period before the first administration/application of the

test or reference item.

測試生物體系於第一次投予試驗物質或參考物質前應先於試驗環境中馴養一段適當時間。

5.2.5 All information needed to properly identify the test systems should appear on their housing or containers. Individual test systems that are to be removed from their housing or containers during the conduct of the study should bear appropriate identification, wherever possible.

適當識別測試體系所需之所有資料，應出現在其房舍或容器上。試驗進行中測試體系個體若由其房舍或容器移出時，不論其可能出現於何處，應佩有適當的識別。

5.2.6 During use, housing or containers for test systems should be cleaned and sanitised at appropriate intervals. Any material that comes into contact with the test system should be free of contaminants at levels that would interfere with the study. Bedding for animals should be changed as required by sound husbandry practice. Use of pest control agents should be documented.

使用測試體系期間，其房舍或容器應定期清潔衛生。任何與測試體系接觸過之物質應避免污染到不干擾試驗之程度。動物墊料應依聲明的照護程序之要求而更換。使用殺蟲劑時應文件記載。

5.2.7 Test systems used in field studies should be located so as to avoid interference in the study from spray drift and from past usage of pesticides.

用於田間試驗之測試體系應界定區域避免受到過去使用農藥噴洒漂散干擾。

**6. Test and Reference Items** 試驗物質與參考物質

6.1 *Receipt, Handling, Sampling and Storage* 配藥、處理、取樣與儲存

6.1.1 Records including test item and reference item characterisation, date of receipt, expiry date, quantities received and used in studies should be maintained.

試驗物質與參考物質之記錄保存應包括特性、取得日期、有效期限、取得量、與試驗用量。

6.1.2 Handling, sampling, and storage procedures should be identified in order that the homogeneity and stability are assured to the degree possible and contamination or mixup are precluded.

處理、取樣、與儲存步驟應確認，以確保均質性與穩定性之程度，並避免被污染與混淆。

6.1.3 Storage container(s) should carry identification information, expiry date, and specific storage instructions.

儲存容器應含識別資料、有效期限、與特別儲存說明。

6.2 *Characterisation* 特性

6.2.1 Each test and reference item should be appropriately identified (e.g., code, Chemical Abstracts Service Registry Number, name, biological parameters).

每一試驗物質與參考物質應予妥適識別(如編碼、CAS 註冊號、名稱、生物參數)。

6.2.2 For each study, the identity, including batch number, purity, composition, concentrations, or other characteristics to appropriately define each batch of the test or reference items should be known.

每次試驗之每批次試驗物質或參考物質的識別包括：批號、純度、成分、濃度、或其它適當之界定特性。

6.2.3 In cases where the test item is supplied by the sponsor, there should be a mechanism, developed in co-operation between the sponsor and the test facility, to verify the identity of the test item subject to the study.

當提供試驗物質由委託者提供時，委託者與檢驗機構之間應建立合作機制以驗證試驗物質確實被委用在試驗中。

6.2.4 The stability of test and reference items under storage and test conditions should be known for all studies.

所有試驗的試驗物質與參考物質在整個試驗中之儲存與試驗條件下的穩定性應被瞭解。

6.2.5 If the test item is administered or applied in a vehicle, the homogeneity, concentration and stability of the test item in that vehicle should be determined. For test items used in field studies (e.g., tank mixes), these may be determined through separate laboratory experiments.

如果試驗物質運用賦形劑投藥處理，試驗物質在賦形劑中的均質性、濃度、與穩定性皆應被測定。用在田間試驗的試驗物質(如混合槽)，上述狀況在試驗中不同階段應予測定。

6.2.6 A sample for analytical purposes from each batch of test item should be retained for all studies except short-term studies.

所有試驗除短期試驗之外，每批試驗物質作為分析用的樣品應予保存。

**7. Standard Operating Procedures** 標準操作程序

7.1 A test facility should have written Standard Operating Procedures approved by test facility management that are intended to ensure the quality and integrity of the data generated by that test facility. Revisions to Standard Operating Procedures should be approved by test facility management.

檢驗機構應有經負責人認可之標準操作程序書，以保證檢驗機構產出之數據資料的品質與完整性。標準操作程序之修訂亦需經檢驗機構負責人認可。

7.2 Each separate test facility unit or area should have immediately available current Standard Operating Procedures relevant to the activities being performed therein. Published text books, analytical methods, articles and manuals may be used as supplements to these Standard Operating Procedures.

每個分開的試驗設施單位或區域應可立即取得與其執行試驗活動有關的最新版標準操作程序書。已發表的教科書及分析方法、報告、與手冊可作為標準操作程序之附件。

7.3 Deviations from Standard Operating Procedures related to the study should be documented and should be acknowledged by the Study Director and the Principal Investigator(s), as applicable.

偏離試驗相關之標準操作程序應書面記載並應為研究主任與試驗主持人所知悉。

7.4 Standard Operating Procedures should be available for, but not be limited to, the following categories of test facility activities. The details given under each heading are to be considered as illustrative examples.

至少下述範圍之檢驗機構活動應具標準操作程序。(每一標題下之細節為舉例)

7.4.1 *Test and Reference Items* 試驗物質與參考物質

Receipt, identification, labelling, handling, sampling and storage.

配方、識別、標織、處理、取樣與儲存。

7.4.2 *Apparatus, Materials and Reagents* 設備、材料與試劑

(a)*Apparatus* 設備

Use, maintenance, cleaning and calibration.

使用、維護、清潔與校正。

(b)*Computerised Systems* 電腦化系統

Validation, operation, maintenance, security, change control and back-up.

驗證、操作、維護、保安、變更控管與備份。

(c)*Materials, Reagents and Solutions* 材料、試劑與溶液

Preparation and labelling. 製備與標示。

7.4.3 *Record Keeping, Reporting, Storage, and Retrieval*

紀錄之保留、報告與存取

Coding of studies, data collection, preparation of reports, indexing systems, handling of data, including the use of computerised systems.

試驗之編碼、資料之收集、報告之準備、檢索之系統、資料之處理、包括電腦化系統之使用。

7.4.4 *Test system where appropriate* 適當的測試體系

(a)Room preparation and environmental room conditions for the test system.

為供試體系準備房間與環境條件。

(b)Procedures for receipt, transfer, proper placement, characterisation, identification and care of the test system.

測試體系之接收、運送、妥適放置、特性、鑑定、與照護的步驟。

(c)Test system preparation, observations and examinations, before, during and at the conclusion of the study.

試驗前、試驗期間與做試驗結論時，測試體系之準備、觀察、與檢驗。

(d)Handling of test system individuals found moribund or dead during the study.

試驗期間發現測試體系瀕死或死亡之處理。

(e)Collection, identification and handling of specimens including necropsy and histopathology.

標本(檢體)之收集、鑑定與處理，包括驗屍與組織病理檢查。

(f)Siting and placement of test systems in test plots.

測試體系在試驗田之設置與擺放。

7.4.5 *Quality Assurance Procedures* 品質保證程序

Operation of Quality Assurance personnel in planning, scheduling, performing, documenting and reporting inspections.

品保人員之稽核計畫、稽核進度、稽核執行、稽核文件化作業、與稽核報告等運作。

**8. Performance of the Study** 試驗研究之執行

8.1 *Study Plan* 試驗計畫

8.1.1 For each study, a written plan should exist prior to the initiation of the study. The study plan should be approved by dated signature of the Study Director and verified for GLP compliance by Quality Assurance personnel as specified in Section 2.2.1.b., above. The study plan should also be approved by the test facility management and the sponsor, if required by national regulation or legislation in the country where the study is being performed.

每一個試驗在試驗開始之前應先寫試驗計畫。試驗計畫應經研究主任簽署押日期批准，並由品保人員依前述之 2.2.1(b)節證明服從 GLP。若執行試驗所在國有國家法規或管理之要求，試驗計畫亦應經檢驗機構負責人與委託者認可。

8.1.2

(a)Amendments to the study plan should be justified and approved by dated signature of the Study Director and maintained with the study plan.

試驗計畫之修訂應經研究主任判斷與簽署押日期認可，並與原試驗計畫一齊保存。

(b)Deviations from the study plan should be described, explained, acknowledged and dated in a timely fashion by the Study Director and/or Principal Investigator(s) and maintained with the study raw data.

偏離試驗計畫應由研究主任與/或試驗計畫主持人及時描述、解釋、通知與簽署日期，並和試驗原始資料一齊保存。

8.1.3 For short-term studies, a general study plan accompanied by a study specific supplement may be used.

短期試驗者可用制式的試驗計畫書附加特別的補充。

8.2 *Content of the Study Plan* 試驗計畫內容

The study plan should contain, but not be limited to the following information：

試驗計畫書至少應包含下列資料：

8.2.1 *Identification of the Study, the Test Item and Reference Item*

試驗、試驗物質與參考物質之識別

(a)A descriptive title；一個描述標題；

(b)A statement which reveals the nature and purpose of the study；

一份可呈現試驗本質與目的之聲明；

(c)Identification of the test item by code or name (IUPAC; CAS number, biological parameters, etc.)；

以編碼或命名(IUPAC、CAS 註冊號、生物參數等)方式識別試驗物質；

(d)The reference item to be used. 將採用之參考物質。

8.2.2 *Information Concerning the sponsor and the test facility*

有關委託者與檢驗機構之資料

(a)Name and address of the sponsor；委託者名稱與住址；

(b)Name and address of any test facilities and test sites involved；

檢驗機構與參與試驗場所之名稱與住址；

(c)Name and address of the Study Director；研究主任之名稱與住址；

(d)Name and address of the Principal Investigator(s), and the phase(s) of the study delegated by the Study Director and under the responsibility of the Principal Investigator(s).

試驗主持人之名稱與住址，與其受研究主任委派試驗部分的責任。

8.2.3 *Dates* 日期

(a)The date of approval of the study plan by signature of the Study Director. The date of approval of the study plan by signature of the test facility management and sponsor if required by national regulation or legislation in the country where the study is being performed.

研究主任簽署核可試驗計畫之日期。若應試驗執行地之國家法規或註冊記要求時，加檢驗機構負責人與委託者簽署認可試驗計畫之日期。

(b)The proposed experimental starting and completion dates.

預計實驗開始與完成日期。

8.2.4 *Test Methods* 測試方法

Reference to the OECD Test Guideline or other test guideline or method to be used.

參照 OECD 檢測指引或其它相關試驗規範與方法。

8.2.5 *Issues where applicable* 合適的發行

(a)The justification for selection of the test system ；

判定選擇之測試體系；

(b)Characterisation of the test system, such as the species, strain, substrain, source of supply, number, body weight range, sex, age and other pertinent information ；

記述測試體系之特性，如物種、品系、亞品系、供應來源、數量、體重範圍、性別、年齡及其它相關資料；

(c)The method of administration and the reason for its choice ；

投藥方法與其擇用理由；

(d)The dose levels and/or concentration(s), frequency, and duration of administration/application ；

投藥/用藥之劑量與/或濃度、頻率、與持續時間；

(e)Detailed information on the experimental design, including a description of the chronological procedure of the study, all methods, materials and conditions, type and frequency of analysis, measurements, observations and examinations to be performed, and statistical methods to be used (if any).

實驗設計之詳細資料，包括試驗步驟順序的描述、所有方法、材料與條件、分析之種類與頻率、執行實驗之量測觀察與檢測、以及任何使用之統計方法。

8.2.6 *Records* 記錄

A list of records to be retained. 所保留紀錄之清單。

8.3 *Conduct of the Study* 試驗之執行

8.3.1 A unique identification should be given to each study. All items concerning this study should carry this identification. Specimens from the study should be identified to confirm their origin. Such identification should enable traceability, as appropriate for the specimen and study.

每一試驗應有獨一之識別。所有與試驗有關之物件皆應含此識別。由試驗而來的標本(檢體)應藉此識別以確認其來源，裨便追溯。

8.3.2 The study should be conducted in accordance with the study plan.

試驗應依試驗計畫進行。

8.3.3 All data generated during the conduct of the study should be recorded directly, promptly, accurately, and legibly by the individual entering the

data. These entries should be signed or initialled and dated.
所有經試驗產出之數據資料應直接、及時、正確、清晰地被獲得數據者記錄，並簽署日期。

8.3.4 Any change in the raw data should be made so as not to obscure the previous entry, should indicate the reason for change and should be dated and signed or initialled by the individual making the change.
任何原始資料之更改，不可塗銷原先之記錄，應由變更者註明更改理由並簽署日期。

8.3.5 Data generated as a direct computer input should be identified at the time of data input by the individual(s) responsible for direct data entries. Computerised system design should always provide for the retention of full audit trails to show all changes to the data without obscuring the original data. It should be possible to associate all changes to data with the persons having made those changes, for example, by use of timed and dated (electronic) signatures. Reason for changes should be given.
直接以輸入電腦方式產出數據時，輸入數據之人員於數據輸入時應立即核對。電腦化系統之設計應可保存用以顯示其所有數據變更未隱蔽原始數據之完整稽核蹤跡。應可將數據更動與執行更動者相連結，如(電子)簽署時間與日期。應註明更動之理由。

**9. Reporting of Study Results** 試驗結果之報告

9.1 *General* 通則

9.1.1 A final report should be prepared for each study. In the case of short term studies, a standardised final report accompanied by a study specific extension may be prepared.
每一個試驗應製備一總結報告。在短期試驗情況者，可用制式報告加特別的補充。

9.1.2 Reports of Principal Investigators or scientists involved in the study should be signed and dated by them.
參與試驗之試驗主持人或研究人員的報告應簽署押日期。

9.1.3 The final report should be signed and dated by the Study Director to indicate acceptance of responsibility for the validity of the data. The extent of compliance with these Principles of Good Laboratory Practice should be indicated.
總結報告應由研究主任簽署日期以示其承諾負責數據之有效性，並指明遵守 GLP 原則的程度範圍。

9.1.4 Corrections and additions to a final report should be in the form of amendments. Amendments should clearly specify the reason for the corrections or additions and should be signed and dated by the Study Director.

總結報告之更正與添加應以修訂方式為之。修訂版報告應清楚界定修正或添加的理由，並由研究主任簽署及押日期。

9.1.5 Reformatting of the final report to comply with the submission requirements of a national registration or regulatory authority does not constitute a correction, addition or amendment to the final report.

為依照國家登記或管理權責單位之提交要求而重製總結報告不含更正、附加或修訂。

9.2 *Content of the Final Report* 總結報告之內容

The final report should include, but not be limited to, the following information：

總結報告至少應含以下資料：

9.2.1 *Identification of the Study, the Test Item and Reference Item*

試驗、試驗物質與對照物質之識別

(a)A descriptive title；一個敘述性標題；

(b)Identification of the test item by code or name (IUPAC, CAS number, biological parameters, etc.)；

以編碼或名稱識別試驗物質 (如 IUPAC、CAS 註冊號、生物參數等)；

(c)Identification of the reference item by name；以名稱識別參考物質；

(d)Characterisation of the test item including purity, stability and homogeneity.

試驗物質之特性，包括純度、穩定性與均質性。

9.2.2 *Information Concerning the sponsor and the test facility*

有關委託者與檢驗機構之資料

(a)Name and address of the sponsor；委託者名稱與地址；

(b)Name and address of any test facilities and test sites involved；

檢驗機構與參與試驗場所之名稱與地址；

(c)Name and address of the Study Director；研究主任之姓名與地址；

(d)Name and address of the Principal Investigator(s) and the phase(s) of the study delegated, if applicable；

試驗主持人之姓名與地址及其被指派之部分；

(e)Name and address of scientists having contributed reports to the final report.

對總結報告有貢獻的科學家姓名與地址。

9.2.3 *Dates* 日期

Experimental starting and completion dates. 實驗起始與完成日期。

9.2.4 *Statement* 聲明

A Quality Assurance Programme statement listing the types of inspections made and their dates, including the phase(s) inspected, and the dates any inspection results were reported to management and to the Study Director and Principal Investigator(s), if applicable. This statement would also serve to confirm that the final report reflects the raw data.

品保計畫聲明列出稽核種類與稽核日期，包括稽核的部分、以及任何稽核結果報告給試驗負責人、研究主任、及試驗主持人的日期。此聲明亦做為確認總結報告確實反映原始數據之用。

9.2.5 *Description of Materials and Test Methods* 試驗材料與方法之描述

(a)Description of methods and materials used；

使用方法與材料之描述；

(b)Reference to OECD Test Guideline or other test guideline or method.

參照 OECD 檢測指引或其它試驗規範或方法。

9.2.6 *Results* 結果

(a)A summary of results；結果之摘要；

(b)All information and data required by the study plan；

試驗計畫要求之全部資料與數據；

(c)A presentation of the results, including calculations and determinations of statistical significance；

結果之表示，包括運算與統計顯著性之決定；

(d)An evaluation and discussion of the results and, where appropriate, conclusions.

結果之評估與討論，若適宜時，做結論。

9.2.7 *Storage* 儲存

The location(s) where the study plan, samples of test and reference items, specimens, raw data and the final report are to be stored.

保存試驗計畫書、試驗物質與參考物質之樣品、標本(檢體)、原始數據資料及總結報告之地點。

**10. Storage and Retention of Records and Materials** 記錄與材料之保存

10.1 The following should be retained in the archives for the period specified by the appropriate authorities：

下列項目應依適當權責單位所指定之期間加以歸檔保存：

(a)The study plan, raw data, samples of test and reference items, specimens, and the final report of each study；

每個試驗之試驗計畫書、原始數據資料、試驗物質與參考物質之樣本、生物標本、及總結報告；

(b)Records of all inspections performed by the Quality Assurance Programme, as well as master schedules；

所有品保系統所執行之稽核紀錄和其主要進度表；

(c)Records of qualifications, training, experience and job descriptions of personnel；

人員之資格、訓練、經驗、與職務說明的記錄；

(d)Records and reports of the maintenance and calibration of apparatus；

儀器設備之維修與校正報告記錄；

(e)Validation documentation for computerised systems；

電腦化系統之驗證文件；

(f)The historical file of all Standard Operating Procedures；

所有標準操作程序之歷史檔案；

(g)Environmental monitoring records. 環境監控記錄。

In the absence of a required retention period, the final disposition of any study materials should be documented. When samples of test and reference items and specimens are disposed of before the expiry of the required retention period for any reason, this should be justified and documented. Samples of test and reference items and specimens should be retained only as long as the quality of the preparation permits evaluation.

無需期限保存之任何試驗材料的最後處置應書面說明。當試驗物質與參考物質之樣品及標本(檢體)在保存期限前因故丟棄者應予判斷並書面說明。試驗物質與參考物質之樣品與標本之保持期限應依其其製備之品質可供評估之期限而定。

10.2 Material retained in the archives should be indexed so as to facilitate orderly storage and retrieval.

保存材料之檔案應有檢索以利存取秩序。

10.3 Only personnel authorised by management should have access to the archives. Movement of material in and out of the archives should be properly recorded.

只有經負責人授權之人員可以整理檔案。檔案內物品之移進移出應適當記錄。

10.4 If a test facility or an archive contracting facility goes out of business and has no legal successor, the archive should be transferred to the archives of the sponsor(s) of the study(s).

如果檢驗機構或檔案承包機構結束營業且無法定繼承者時，所有檔案應轉移到試驗委託者。