藥品非臨床試驗優良操作規範

(Good Laboratory Practice for Nonclinical Laboratory Studies)

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中華民國八十七年六月初版
中華民國八十七年九月再版
中華民國八十九年六月三版

目　　錄

序　言

民國八十四年八月十日行政院第二四四三次院會通過「加強生物技術產業推動方案」，其中健全生物技術醫藥開發之法令規範，以提高我國生物技術產業之發展，為重要主題之一。隨著醫藥品科技之進步，生活中所使用藥品的種類與數量都有增加。同時由於醫藥科技工業的進步，國人對藥品使用之安全性及副作用的控制之要求也相對提高。在目前國際化的環境下，醫藥品的使用不單是限於一個國家的產品，也會使用其他不同國家輸入的製品，因此對藥品安全性的保證也需要考慮到國外產品安全性之可靠性。

在研發藥品過程中，動物試驗是確保藥品安全性的重要途徑之一，為了確保這些產品安全試驗足以信賴，確有制訂「藥品非臨床試驗優良操作規範」之必要性。

我國目前已將製藥工業及生物科技列為重要的發展方向之一。為提升我國製藥產品品質，建立良好形象，以增加醫藥品的輸出，加強國際競爭能力以進入國際市場，推動相互認證制度，加入世界貿易組織及相關國際組織，實施 GLP (Good Laboratory Practice) 確為迫切的需要。

世界各國為避免在進行藥品研發之各項動物試驗時無謂的重覆與浪費，多採用一致性的國際認證標準。目前有關醫藥品之GLP，主要有由美國食品藥物管理局 (FDA) 所制訂者(其採用國家如加拿大)；由日本厚生省及瑞士所制訂者；由Organization for Economic Cooperation and Development (OECD) 所制訂者 (如比利時)，以及 OECD 會員國(如法國、英國等)依據 OECD 規範所另行制訂適合該國之 GLP 等。本署為提昇藥品動物試驗水準，確保試驗品質及數據之可信度及完整性，依據 OECD、美國 FDA、日本厚生省之 GLP 及我國優良藥品製造標準 (GMP) 與中華藥典等資料，歷經十餘次會議

討論，於民國七十九年制訂完成「優良實驗操作規範」。本「藥品非臨床試驗優良操作規範」之制訂，係以美國 FDA 之「Good Laboratory Practice for Nonclinical Laboratory Studies」為藍本，並以美國 FDA 及我國之「優良實驗操作規範」為本規範之架構，再參照各國之 GLP 條款及我國相關法規，訂定適合我國及符合國際共通性之 GLP。

本草案經召集國內各學術、學會及公會等有關機關集會討論並彙整各相關單位意見後，訂為「藥品非臨床試驗優良操作規範」。本規範之訂定將提供我國藥品研發進行動物試驗可參照之準則，以確保各項試驗數據之完整性與可信度，並作為日後進行藥品查驗登記時審查動物試驗之依據。

藥政處

三 版 序 言

本署衛署藥字第87040892號公告『藥品非臨床試驗優良操作規範』於中華民國八十七年六月二十九日公告後，於同年六月發行單行本，迅即再版(同年九月)。今將修正部份予以公告(修正部份以黑粗字體表示)，同時也印製單行本，以供業界與專家學者參考。

藥政處

藥品非臨床試驗優良操作規範

第壹章　總則

一、藥品非臨床試驗優良操作規範(以下簡稱本規範)，**係提供藥品研發評估及藥品查驗登記申請文件中的非臨床試驗應遵循之規範**，以確保各項試驗數據之品質及試驗之完整性與可信度。

二、本規範專有名詞之定義如下：

(一)　實驗室優良操作規範 (Good Laboratory Practice, GLP)

實驗室優良操作規範係指有關實驗室試驗之計畫、執行、監測、記錄、報告及檔案的組織架構及規範。

(二)　非臨床試驗 (Nonclinical Laboratory Study)

非臨床試驗(以下簡稱試驗)係指於實驗室條件下之試驗體系，用活體內或活體外試驗來測試試驗物質的安全性。此試驗並不包括人體試驗或臨床試驗。亦不包括測試試驗物質是否具有任何潛在用途或針對其物理或化學性質所作的基礎性研究。

(三)　試驗機構 (Testing Facility)

試驗機構係指包括執行試驗所需之人員、設施、設備及作業部門。

(四)　試驗機構負責人 (Management)

試驗機構負責人係指管理該試驗機構整體作業之負責人。

(五)　試驗主持人 (**Study Director**)

試驗主持人係指執行該試驗之負責人。

(六)　試驗委託者 (Sponsor)

試驗委託者係指提供試驗之財務或其他資源；或將試驗結果向中央衛生主管機關申請藥品查驗登記之個人或法人，亦可為執行試驗之試驗機構。

(七) 品質保證單位 (Quality Assurance Unit)

品質保證單位係指為確保試驗符合本規範之規定，由試驗機構負責人指定執行品質保證工作之未參與此研究之人員或組織。

(八) 試驗體系 (Test System)

試驗體系係指試驗中用來測試試驗物質或對照物質之動物、植物、微生物、細胞**或**其組成部份，化學或物理等體系或其合併體系。

(九) 試藥與溶液 (Reagents and Solutions)

試藥與溶液係包括試藥、試液、溶劑、指示劑、試紙、比色溶液及容量分析溶液等。

(十) 試驗物質 (Test Article)

試驗物質係指任何待測之藥品、化學、生物物質**或**其混合物。

(十一) 對照物質 (Control Article or Reference Article)

對照物質係指於試驗期間，用以與試驗物質比較之藥品、化學、生物物質或其混合物。

(十二) 賦形體 (Vehicle or Carrier)

賦形體係指用來混合、分散或溶解以利於試驗物質或對照物質投予試驗體系之媒介物質。

(十三) 批 (Lot (or Batch))

批係指如本規範第陸章第一項所述之特定數量之試驗物質或對照物質，其具有均一之特性與品質。

(十四) 樣品 (Sample)

樣品係指定量之試驗物質或對照物質。

(十五) 標本 (Specimen)

標本係指由試驗體系衍生而來用於檢查或分析之物質。

(十六) 原始數據 (Raw Data)

原始數據係指於試驗過程中為整理或評估試驗報告所需保留之任何觀察結果、原始紀錄、文件或其精確複印本。原始數據可包括相片、微縮影片、電腦列印報表、磁性媒體及自動裝置等所得到之觀察數據或其紀錄。

三、試驗委託者對受託試驗機構之通知

試驗委託者申請受託試驗機構進行試驗時，試驗委託者必須事先通知受託試驗機構遵照本規範進行試驗。

四、查核

(一) 中央衛生主管機關為確認試驗之可信度及完整性，試驗機構應允許其查核人員查核依本規範之設施及保存之文書紀錄、標本等；查核人員得影印或以其他適當方法複製該文書紀錄或其副本。

(二) 前款所述之查核，必要時中央衛生主管機關得指定適當人員查核；或邀請有關機關或專家參加查核。

第貳章　組織與人事

一、組織

試驗機構內置試驗機構負責人負責整體試驗之管理，且每一試驗計畫應有一試驗主持人負責試驗之執行，並應設品質保證單位稽查各項試驗工作以確保其執行過程均符合本規範之要求。

二、人員管理

(一)　參與執行的每一位人員及負有監督責任者必須具備相當之教育、訓練、經驗或兼具而能勝任其職務。

(二)　應以書面制訂試驗機構內每一職位之工作職責，並應確實遵行之。

(三)　應保存實際參與試驗者之學歷背景、經歷、曾接受有關訓練及工作職責等之最新資料。

(四)　應依據試驗計畫書之要求，提供足夠之人員參與試驗工作。

(五)　應制訂新進及在職人員應有之訓練程序，以確保每一位試驗人員均能勝任其職務，且應將訓練內容及結果作成完整之紀錄。

(六)　試驗操作人員應注意個人衛生及健康，以防止污染試驗物質、對照物質及試驗體系等。

(七)　參與試驗者發現罹患足以影響試驗可信度之疾病應報告其監督者，應避免參與試驗，與試驗物質、對照物質及試驗體系接觸，以免影響試驗品質及其完整性，直至其恢復健康狀況。

(八)　參與試驗者應配合工作性質穿著適當之工作衣物(包括護鏡、保護衣、口罩、手套、鞋、襪等)執行工作，並依需要經常換洗，以防止來自試驗物質、對照物質及試驗體系之微生物、放射性物質或化學性物質等之污染。

(九) 試驗人員應配合工作性質接受定期健康檢查。

(十) 試驗人員必須遵守實驗室安全及其有關規定執行試驗。

三、試驗機構負責人

試驗機構負責人應確保試驗機構依照本規範執行，並確保下列事項：

(一) 確保每一試驗開始前均有一指定如本章第四項所述之試驗主持人負責該試驗之執行。

(二) 於試驗過程中視需要可即時更換試驗主持人，惟其更換事宜應作成書面紀錄。

(三) 制訂實驗安全措施以確保實驗室安全。

(四) 設立如本章第五項所述之品質保證單位，並確保其功能符合本規範之規定。

(五) 確保試驗物質、對照物質或其混合物於必要時進行適當之鑑別，並測試其含量、純度、安定性及均一性等試驗。

(六) 確保人員、試驗材料、經費、設施、儀器、設備及試驗方法均依既定計畫執行之。

(七) 確保每一試驗均依既定之標準操作程序執行，而其安全及衛生規定皆符合國家有關法令之要求。

(八) 確保試驗人員都確切明瞭其執行之工作。

(九) 確保當試驗執行與本規範有所偏差時，品質保證單位應通知試驗主持人採取改善補救措施並作成書面紀錄。

(十) 必要時與試驗委託者共同同意試驗計畫書。

(十一) 確保試驗計畫書、有關之標準操作程序及其制訂歷程檔案均妥善保存。

(十二) 確保試驗計畫書之修訂確經同意並予以詳確記錄。

(十三) 應指定一位經授權之人員負責管理檔案室。

四、試驗主持人

試驗主持人應由具備相當教育、訓練、經驗或兼具之科技專業人員擔任。試驗主持人對試驗之執行及管制，試驗結果之解釋、分析、紀錄及報告等負整體之責任並應確保下列事宜：

(一) 試驗計畫書及其任何變更事項，均依照本規範第七章之規定審核後執行。

(二) 所有試驗數據包括試驗體系中非預期之觀察結果，均經詳確記錄及審核。

(三) 試驗過程中，足以影響試驗品質及其完整性之突發狀況與所採取之補救措施，均經詳確記錄。

(四) 所使用之試驗體系符合試驗計畫書之規定。

(五) 試驗程序均依本規範規定執行。

(六) 所有原始數據、紀錄、試驗計畫書、標本及總結試驗報告等，於試驗過程或試驗終了均予以歸檔。

五、品質保證單位

(一) 試驗機構應設品質保證單位，負責稽查試驗計畫之執行過程，以確保其設施、設備、儀器、人員、試驗方法、各項管制及紀錄等符合本規範之要求。

(二) 執行品質保證工作人員應熟悉該試驗且經有關訓練並由不參與該試驗之人員擔任。

(三) 品質保證單位之職責及作業程序：

1. 負責保存**一份所有在試驗機構裏進行試驗之主計畫進度表(依試驗物質製作索引)，內容包括試驗物質或成分、試驗體系、試驗性質，試驗執行日期、各試驗階段、試驗委託者姓名、試驗主持人姓名及總結試驗報告**。

2. 對負責稽查之試驗**保存一份其試驗計畫書**。

3. 定期稽查各試驗階段以確保所執行之試驗符合試驗計畫書及標準操作程序，將稽查試驗結果及內容、稽查所發現問題之缺失及改進措施與再稽查日期等製作成報告並簽署後保存。試驗階段應適當的間隔定期稽查，以確保試驗之可信度及完整性。稽查過程中如發現影響試驗可信度及完整性之重要問題時，應立刻報告試驗主持人及試驗機構負責人。

4. 應對負責稽查之試驗定期提出稽查試驗之現階段書面報告，簽具問題缺失並提具體修正措施，並送交試驗機構負責人及試驗主持人。

5. 應確定所稽查之試驗其執行與標準操作程序或核准之試驗計畫書無未經審核之任何偏差發生。

6. 稽查總結試驗報告時應確定該報告正確地記載試驗方法，且其結果正確反映試驗之原始數據。

7. 稽查終了應簽署一份報告併於總結試驗報告送交試驗主持人及試驗機構負責人，該報告應載明稽查日期及於稽查過程中所發現之缺失及改進措施。

(四) 品質保證單位之職責及其作業程序以及編索有關紀錄的方法均應制訂標準操作程序並保存遵行之。所有保存之紀錄應包括稽查日期、試驗名稱、試驗階段及稽查者之簽名、簽註日期。

(五) 所有品質保證單位保存之紀錄應存放於試驗機構備查。

第參章　設施

一、一般規定

試驗機構應具有適當之配置、空間及構造以利試驗之執行，且其設計須有適當程度之隔離，以避免**任何功能或活動對試驗產生不良的影響**。

二、動物管理設施

(一)　動物管理設施之設計、構造及配置應以對試驗之干擾降至最低為原則。

(二)　為確保動物品種(系)或試驗體系之區分、個別計畫之獨立、動物檢疫之隔離、一般或特定動物之飼養，必要時應設足夠的動物飼養場所。

(三)　當使用之試驗體系或試驗物質及對照物質具有生物危險性(包括揮發性、放射性、傳染性物質及噴霧劑等)時，應具足夠之動物飼養場所以供與前款之場所分開。

(四)　應提供適當的場所作為診療及控制試驗動物疾病之用，且應提供已知或疑似染有疾病之動物、帶菌者與其他動物作有效隔離的場所。

(五)　動物飼養場所應有收集及衛生處理試驗體系所產生之排泄物、廢棄物之設施，若無前述設施則於運出試驗機構前應予安全且衛生之儲存。該處理設施應具有將疾病、氣味、害蟲孳生和環境污染降至最低之功能。

三、動物用品供給設施

試驗機構內必要時應具備儲存飼料、床敷、墊料、飼養用品及器具之場所，且飼料、床敷及墊料的儲存場所與試驗體系之飼養場所分開，以防止污染。易腐爛之用品或飼料應以適當方法儲存之。

四、試驗物質及對照物質之管理設施

(一) 為防止污染及混淆，試驗機構應有下列區域：

1. 試驗物質及對照物質之驗收、儲存及處理場所。

2. 試驗物質、對照物質與賦形體之調和場所。

3. 前述混合物之儲存場所。

(二) 前款所列工作區域應與試驗體系之飼養場所隔離，並確保試驗物質或對照物質及其混合物之力價、純度、均一性及安定性。

五、試驗操作區域

試驗機構應具有足敷試驗所需之設施，且應視需要提供適當之隔離試驗場所，以執行所需之例行工作及特定工作，其試驗場所之設置條件應配合工作之需要。

六、標本、紀錄與報告之管理設施

應提供存放與檢索所有試驗計畫書、原始數據、標本、樣品、文書紀錄與報告之場所，此場所非經授權不可進入。

七、實驗室安全及廢棄物處理設施

實驗室之安全防護及廢棄物之處理應符合法令規章。

第肆章　設備

一、一般規定

(一) 用於數據之產生、處理及評估之儀器或器具以及環境管制所需之機器，應具有適當的設計及足夠功能，且其配置應便於操作、檢查、清潔與維護。

(二) 有關物理、化學及生物等各項試驗，應視其需要設置所需之設備，且其設置之條件應能配合工作需要，並妥為配置及維護。

(三) 用於試驗之儀器及器材選擇以對試驗體系或試驗目的之干擾降至最低為原則。

二、維護與校正

(一) 用於數據之產生、處理或評估之設備應予適當之清潔、定期維護及校正。

(二) 應制訂有關操作、稽查、校正及維護儀器、器具、裝置、儀表及記錄器等之標準操作程序，明確規定其校正、維護方法及頻率。標準操作程序中對前述各項工作應指定專人負責。

(三) 前款設備經校正，若發現未能符合其精確度界限，應限制使用並採取補救措施。

(四) 所有儀器操作、稽查、維護及校正紀錄均應予保存，前述紀錄應含各項工作之日期，並註明其操作維護是否依照既定之標準操作程序進行。若因儀器功能失常所執行之非例行性修護工作，其紀錄應記載該缺點發生時間、原因以及所採取之補救措施。

第伍章　試驗機構之操作

一、標準操作程序

(一)　為提高試驗數據之品質及確保試驗之完整、安全性，應依本規範制訂各項標準操作程序，並經試驗機構負責人審核後實施。

(二)　標準操作程序應存放於各有關之試驗場所。其他發表之文獻、書籍或實驗手冊等可作為標準操作程序之補遺。

(三)　試驗中各項操作與既定之標準操作程序有所偏差時應予記錄，並由試驗主持人作合理的判釋。重大的變更則必須經試驗機構負責人審核，並保存書面紀錄。

(四)　標準操作程序修訂時，均應經試驗機構負責人核准。有關標準操作程序之制訂歷程及修訂版應予保留。

(五)　標準操作程序原則上需涵蓋下列各款有關項目：

1. 儀器及器具之使用與管理。
2. 機器及設備之使用與管理。
3. 試藥及溶液之管制。
4. 試驗物質及對照物質之管制。
5. 試驗方法。
6. 動物及動物房之管理。
7. 實驗動物之鑑定、房舍、配置及運送。
8. 試驗體系之觀察及調查。
9. 瀕死及死亡動物之處理。
10. 實驗動物之活體解剖及死體解剖之檢查。

11. 標本之收集、鑑定及管理。

12. 組織病理學之檢查。

13. 紀錄與報告之管理。

14. 品質保證工作之執行。

15. 試驗安全衛生管制。

16. 廢棄物處理

17. 其他有關事項之管制。

二、生物試驗體系

(一) 進口、購買、飼(培)養或使用動物、植物、微生物及細胞等，應依據國家有關之法令規定辦理。

(二) 動物、植物、微生物及細胞之購買、飼(培)養及使用應具有標準操作程序，並保存其紀錄以供追溯瞭解其使用歷程。

(三) 新購進之動物、植物等在未評估其健康狀態前應予隔離檢疫，若觀察期間有異常疾病或死亡時，該批動物、植物等不得供試驗使用，並予適當處置。

(四) 動物、植物、微生物及細胞等於試驗前，應經適當之適應期後始得供試驗。

(五) 在試驗開始時，動物不應有干擾試驗之任何疾病或不良健康狀況發生，若於試驗中有上述情形發生，則該動物應予隔離，必要時對已感染疾病或有疾病徵兆之動物應予治療，而此治療不得對試驗有任何干擾，診療過程及日期均應予記錄保存。

(六) 試驗過程必須長期處理或觀察，或因各種原因必須從籠中取出或送回之溫血動物(未斷乳之嚙齒類動物除外)，應有明確之識別方法。每一動物飼養容器外應有明顯之標識，以確認容器內每一試驗動物。

(七) 不同品種(系)的動物必要時應分別飼養於個別的場所，而相同品種(系)用於不同試驗的動物，若可能因不慎暴露於試驗物質、對照物質或其混合物而影響試驗結果時，原則上不可置於同一室，若必須置於同一室者，則應有適當空間之隔離及明確標示。

(八) 動物飼養場所、動物籠、架及其他附屬器皿、裝置等應定期清洗與衛生處理。

(九) 動物籠或盤內所使用之床敷、墊料應不得干擾試驗目的或試驗進行，且應視需要予以更換，以保證動物置於乾燥和清潔之環境。

(十) 動物飲水及飼料應定期分析，以確定對試驗產生可能干擾之污染物無超過試驗計畫書內規定的容許範圍，其結果應以原始數據之方式保存。

(十一) 使用殺蟲劑時應予記錄，若清潔劑及殺蟲劑會干擾試驗時則不可使用。

三、試藥與溶液之管制

試驗中使用之試藥與溶液應標示其內容物、濃度、儲存條件、配製日期**及有效期限(或再驗日期)。未標示有效期限之試藥與溶液應予重行檢驗**。變質或超過有效期限者不得使用。

第陸章　試驗物質及對照物質

一、試驗物質與對照物質之特性

(一)　試驗開始前應確定每批試驗物質或對照物質之本質、力價、純度、組成或其他可以確切顯示該等物質之特性，並予以記錄。試驗機構或試驗委託者應記錄試驗物質及對照物質之合成、製造方法或來源。若以市售商品為對照物質，其特性可用其確定之標誌代替。

(二)　試驗機構或試驗委託者應在開始進行各項試驗前，應確定試驗物質或對照物質之安定性；或依據既定之標準操作程序定期檢驗之。

(三)　試驗物質及對照物質之每一貯存容器均標示其名稱、編號(代碼)、批號及有效期限，必要時應標示儲存條件。試驗過程中特定試驗物質應置於適當容器貯存之。

(四)　試驗物質之留樣—試驗物質與對照物質每一批均應留存具代表性之儲備樣品，其存放條件應與標示者相同。

儲備樣品之保存期限至少應予留存至試驗結束；當試驗期間超過四週時，向中央衛生主管機關申請藥品查驗登記者，其儲備樣品保存至核准上市後至少二年；其未申請者亦應保存至試驗完成或終止後至少二年。於儲存過程中易腐壞或不安定者應保存至該物質之品質可評估之最後期限。

二、試驗物質與對照物質之管制

應制訂試驗物質及對照物質之管制作業程序，並確保下列各事項：

(一)　適當之儲存。

(二)　處理及輸送過程具有適當之標識，且確保未受任何污染、變質或損毀。

(三)　具有驗收、取樣、儲存及處理之標準操作程序及紀錄，此紀錄應含品名、數量、日期及處理狀況。

三、試驗物質、對照物質與賦形體之混合

(一) 每批試驗物質、對照物質與賦形體之混合，應以適當方法分析下述各項：

1. 確定試驗物質或對照物質與賦形體混合物之均一性，並定期測試混合物中試驗物質或對照物質之濃度。

2. 依據試驗條件，在開始進行各項試驗前，應確定在賦形體混合物中試驗物質或對照物質之安定性；或遵照既定之標準操作程序定期檢驗之。

(二) 試驗物質或對照物質之賦形體混合物中有一成分具有效期限，則應加以標示該期限，若不只一成分具有效期限者，應以其最早失效日期標示之。

第柒章　試驗計畫書及試驗之執行

一、試驗計畫書

(一)　各項試驗應於試驗前撰寫明確顯示試驗目的及方法試驗計畫書，並經試驗機構負責人(含試驗委託者)核准及保存之。上述試驗計畫書需記載下列有關事項：

1. 試驗名稱、性質及目的。
2. 執行試驗之試驗機構及試驗委託者之名稱及住址。
3. 試驗主持人姓名。
4. 試驗所需人力。
5. 試驗開始及結束預定日與預定進度。
6. 對照物質及試驗物質應有足以識別之名稱、編號或代碼。
7. 試驗設計之敘述，包括取樣計畫及偏差管制的方法。
8. 試驗方法(含執行試驗之調查、分析、測定及觀察之種類與頻度)。
9. 試驗體系選擇之理由。
10. 試驗體系之特性描述，例如生物之名稱、數量、體重範圍、年齡、性別、供應來源、品種、品系及其他有關資料。
11. 試驗體系之識別法。
12. 用於動物試驗過程中之溶劑、乳化劑、飼料、飲水等之敘述或鑑別。若已知上述物質中含有影響試驗結果之污染物質，則須明定該污染物質之容許範圍。
13. 投予途徑及選擇該途徑之理由。
14. 投予劑量、方法及頻率。

15. 統計方法之敘述。

16. 試驗機構負責人(含試驗委託者)之認可日期與試驗主持人之簽名及簽註日期。

17. 需保存紀錄與資料之項目。

(二) 經核准之計畫書需作任何修訂或變更時，均應經試驗主持人核准簽名及簽註日期，且需註明其修訂原因並與試驗計畫書保存之。

二、試驗之執行

(一) 任何試驗均應依據試驗計畫書及有關之標準操作程序執行，並予以追蹤管制。

(二) 每一試驗均應有一明確的標示，試驗過程中所使用試藥、溶液及標本等應予明確之標示。

(三) 標本應以適當方法標示試驗種類、試驗體系之編號及採集日期。

(四) 解剖取得標本之肉眼觀察應予以記錄，以便執行組織病理學檢查之人員參考。

(五) 試驗所得到數據之記錄及變更，應遵循下列各事項：

1. 試驗過程中產生之數據，均應以不可塗銷之方法直接、迅速、清晰、正確地予以記錄，並簽名及簽註日期。

2. 自動數據收集系統產生之數據，於輸入時應由負責鍵入者予以確認簽名及簽註日期。

3. 任何資料、數據於變更時亦應保留其原始數據，且註明變更原因、日期及確認者簽名。自動數據收集系統產生之數據，鍵入不清楚需變更時，應註明變更原因及鍵入者予以確認簽名及簽注日期。

(六) 試驗進行中有任何異常或非預期之現象時，參與試驗人員應迅速向試驗主持人報告並詳細記錄之。

第捌章　紀錄與報告

一、總結試驗報告

(一)　每一試驗終了時均應依試驗計畫書撰寫總結試驗報告，內容至少需包括下列事項：

1. 試驗名稱、性質及目的。
2. 試驗機構單位名稱及地址。
3. 試驗之開始及完成日期。
4. 試驗方法之依據(含執行試驗之調查、分析、測定及觀察之種類與頻度)。
5. 取樣及試驗過程中所產生數據之完整紀錄，包括儀器輸出之原始資料及圖譜等。
6. 對照及試驗物質之名稱、編號或代碼、批號、力價、純度及組成或其他適當之特性描述以確認該等物質。
7. 試驗物質及對照物質於既定之投予條件下之安定性。
8. 試驗體系之特性描述，例如生物之名稱、數量、性別、體重範圍、供應來源、品種、品系與其他有關資料及其識別程序。
9. 投予劑量、途徑、頻率及投予期間之記載。
10. 試驗主持人及參與試驗人員姓名與業務分配。
11. 分析數據所用之統計方法及演算公式。
12. 可能影響數據品質及試驗完整性之因素。
13. 試驗數據之運算，分析及其導出之結論及試驗結果之評估判定與摘要(包括參與試驗人員個別報告之簽名及簽註日期)。

14. 標本、原始數據及總結試驗報告之儲存場所及期限。

15. 原始試驗計畫書之任何變更事項。

16. 品質保證單位依本規範第二章規定作成之報告。

(二) 具結確認數據之真實性及試驗程序均依本規範規定執行，並於總結試驗報告應經試驗主持人簽名。

(三) 總結試驗報告之補充或修正應由試驗主持人依一定程序修訂之，且於該報告中清楚顯示其為增補或修正部份，且載明其理由，並由修訂者簽名及簽註日期並由試驗主持人確認之。

二、紀錄及報告之儲存與追溯

(一) 試驗產生之所有原始數據、標本(致突變性試驗及血液、尿糞、生物體液得到之標本除外)、紀錄文書、試驗計畫書和總結試驗報告應建檔並予保存。

(二) 所有原始數據、標本、紀錄文書、試驗計畫書、中間及總結試驗報告均應依序存檔且利於追溯。其儲存狀況應以避免變質為原則，且保存場所應有降低至最小損害之設計；試驗機構亦可委託檔案保管機構提供其適當保存場所。若標本或原始數據與總結試驗報告分開建檔保存時，總結試驗報告之檔案應予詳確記錄。

(三) 紀錄及報告之儲存場所應有特定人員負責管理且非經授權不可進入。進出檔案室之物品應予記錄。

(四) 因試驗規定必須儲存之物質及其有關資料應依序編索以利追溯，例如試驗名稱、試驗物質、試驗日期、試驗體系及試驗本質等之索引。

三、紀錄及報告之保存期限

(一) 試驗產生之所有原始數據、標本(致突變性試驗及血液、尿糞、生物體液得到之標本除外)、紀錄文書、標準操作程序及其制訂歷程、主計畫進度表、試驗計畫書和總結試驗報告等，向中央衛生主管機關申

請藥品查驗登記者，保存至核准上市後至少五年；其未申請者亦應保存至試驗完成或終止後至少二年。

(二) 除前款規定外，溼性標本(致突變性試驗及血液、尿糞、生物體液得到之標本除外)、試驗物質或對照物質樣品及經特別處理之物質，保存過程易顯著變質者，應保存至該物質可評估之最後期限。

(三) 品質保證單位之主計畫進度表、稽查紀錄及負責稽查之試驗計畫書影本均應依序歸檔，並依本章第三項第一款之規定保存於品質保證單位。

(四) 所使用儀器之檢查、保養及校正紀錄，應依本章第三項第一款之規定保存。

(五) 依據本規範第二章之規定有關參與試驗人員之職責、訓練過程及學經歷背景等資料應依本章第三項第一款之規定保存。

(六) 本項之紀錄文書得以原始紀錄文書、相片、顯微影片、電子紀錄或其他精確產生之原始紀錄文書之真實複印本保存之。

(七) 若試驗機構或委託檔案保管機構結束營運時，本項所述之所有原始數據、紀錄文書、及相關資料檔案應轉移繼任試驗機構；若無法定繼任者時，則轉移試驗委託者指定之檔案室。

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附　　表

表1 各國ＧＬＰ內容要件

中華民國	日　　本	美　　國	ＯＥＣＤ	法　　國	瑞　　士	英　　國	藥物食品檢驗局
第壹章 總則 ＊ 目的 ＊ 專有名詞之定義 ＊ 試驗委託者對受託試驗機構之通知 ＊ 查核	Chapter I General Provision ＊ Purpose ＊ Definitions ＊ Notification to a contract laboratory by a sponsor ＊ Inspection	Subpart A General Provision ＊ Scope ＊ Definitions ＊ Applicability to studies performed under grants and contracts ＊ Inspection of a testing facility	Section I Introduction ＊ Preface ＊ Scope ＊ Definitions of terms	Section I Introduction ＊ Scope ＊ Definitions of terms ＊ Application to the studies preformed under grants or contracts	Subpart A General Provisions ＊ Scope ＊ Definitions ＊ Applicability to studies performed under contract	Definition	第一篇　總則 ＊ 範圍 ＊ 定義
			Section II Good Laboratory Practice Principles	Section II Good Laboratory Practice Principles			
第貳章 組織與人事 *組織 *人員管理 *試驗機構負責人 *試驗主持人 *品質保證單位	Chapter II Personnel and Organization ＊ Personnel ＊ Management ＊ Study director ＊ Quality assurance unit	Subpart B Organization and Personnel ＊ Personnel ＊ Testing facility management ＊ Study director ＊ Quality assurance unit	1. Test Facility Organization and Personnel ＊ Management's responsibilities ＊ Study director's responsibilities ＊ Personnel responsibilities 2. Quality Assurance Programme ＊ General ＊ Responsibilities of quality assurance personnel	1. Organization and Personnel of a Test Facility for Experimental Toxicity Studies ＊ Management's responsibilities ＊ Study director's responsibilities ＊ Personnel responsibilities 2.Quality Assurance Programme ＊ General ＊ Responsibilities of the personnel performing the quality assurance programme	Subpart B Organization and Personnel ＊ Research facility management ＊ Personnel ＊ Study director ＊ Quality assurance program	Management ＊ Personnel ＊ Facilities and operational requirements Quality Assurance	第三篇　試驗操作規範 第一章 組織與人事 *試驗機構 *試驗主持人 *人員管理 第七章 品質保證單位
第參章 設施 ＊ 一般規定 ＊ 動物管理設施 ＊ 動物用品供給設施 ＊ 試驗物質及對照物質之管理設施 ＊ 試驗操作區域 ＊ 實驗室安全設施 ＊ 標本、紀錄與報告之管理設施 ＊ 實驗室安全及廢棄物處理設施	Chapter III Facilities ＊ General ＊ Animal care facilities etc. ＊ Animal supply facilities ＊ Facilities for handling test and control articles ＊ Laboratory operation areas ＊ Archives ＊ Administrative facilities etc.	Subpart C Facilities ＊ General ＊ Animal care facilities ＊ Animal supply facilities ＊ Facilities for handling test and control articles ＊ Laboratory operation areas ＊ Specimen and data storage facilities ＊ Administrative and personnel facilities	3. Facilities ＊ General ＊ Test system facilities ＊ Facilities for handling test and reference substances ＊ Archive facilities ＊ Waste disposal	3. Facilities ＊ General ＊ Test system facilities ＊ Facilities for handling test and reference articles ＊ Archive facilities ＊ Waste disposal	Subpart C Facilities ＊ General *Test system care facilities ＊ Facilities for handling test , control and comparison substances/articles ＊ Laboratories ＊ Specimen and data storage facilities	Facilities ＊ Facilities for experiment animals ＊ Facilities for handling test substances ＊ Laboratory operation area ＊ Archives	第二篇　設施及設備 第一章設施 *一般規定 *試驗操作設施 *動物管理設施 *試驗物質及對照物質之管理設施 *標本、紀錄與報告之管理設施 *實驗室安全設施 *廢棄物處理設施

表1 各國ＧＬＰ內容要件(續前頁)

中華民國	日　　本	美　　國	ＯＥＣＤ	法　　國	瑞　　士	英　　國	藥物食品檢驗局
第肆章 設備 ＊ 一般規定 ＊ 維護與校正	Chapter IV Equipment ＊ Design and function of equipment ＊ Location of equipment ＊ Equipment Control	Subpart D Equipment ＊ Equipment design ＊ Maintenance and calibration of equipment	4.Apparatus, Material, and Reagents ＊ Apparatus ＊ Material ＊ Reagents	4.Appartus, Material, and Reagents ＊ Apparatus ＊ Material ＊ Reagents	Subpart D Equipment ＊ Equipment design ＊ Maintenance and calibration of equipment	Equipment	第二章 設備 *一般規定 *維護與校正
第伍章 試驗機構之操作 ＊ 標準操作程序 ＊ 生物試驗體系 ＊ 試藥與溶液之管制	Chapter V ing Facilities Operation ＊ Standard operating procedures ＊ Reagents and solution ＊ Animal care	Subpart E ing Facilities Operation ＊ Standard operating procedures ＊ Reagent and solution ＊ Animal care	5.Test System ＊ Physical/Chemical ＊ Biological 7.Standard Operating Procedures ＊ General ＊ Application	5. Test System ＊ Biological 7.Standard Operating Procedures ＊ General ＊ Application	Subpart E Research Facilities Operation ＊ Working instructions ＊ Regent and solution ＊ Handling of test animals	Testing Facility Working Procedure ＊ Standard operating procedures ＊ Handling of animals and other biological test system ＊ Reagents and solution ＊ Test substance	第三篇 試驗操作規範 第三章 標準操作程序 第四章 生物試驗體系 第五章 試驗與溶液之管制
第陸章 試驗物質及對照物質 ＊ 試驗物質與對照物質之特性 ＊ 試驗物質與對照物質之	Chapter VI Test and Control Articles ＊ Test and control article characterization ＊ Test and control article	Subpart F Test and Control Articles ＊ Test and control article characterization ＊ Test and control article	6.Test and Reference Substances *Receipt, handling, sampling, and storage *Characterization	6.Test and Reference Substances ＊ Receipt, handling, sampling, and storage ＊ Characterization	Subpart F , Control and Comparison Articles ＊ Characterization of the articles		第六章 試驗物質及對照物質之管制

管制 * 試驗物質、對照物質與賦體之混合	handing * Mixtures with carriers	handling * Mixture of articles with carriers			* Handling of articles * Mixture of articles with carriers		
第柒章 試驗計畫書及試驗之執行 * 試驗計畫書 * 試驗之執行	Chapter VII ocol for and Conduct a Study * Protocol * Conduct of a study	Subpart G ocol for and Conduct of a Nonclinical Laboratory Study * Protocol * Conduct of a nonclinical laboratory study	8.Performance of the Study * Study plan * Content of the study plan * Conduct of the study	8.Performance of the Study * Protocol * Content of the protocol * Conduct of the study	Subpart G nning and Conduct of a Study * Protocol * Conduct of the study	nning and Conduct of Study * Study plan * Conduct of the study	第二章 * 試驗計畫書 * 試驗之執行
		Subpart H-I Reserved					

表1 各國ＧＬＰ內容要件(續前頁)

中華民國	日　　本	美　　國	ＯＥＣＤ	法　　國	瑞　　士	英　　國	藥物食品檢驗局
第捌章 報告與紀錄 * 總結試驗報告 * 紀錄及報告之儲存與追溯 * 紀錄及報告之保存期限	Chapter VIII Reports and Records * Final report * Storage and retrieval of records and specimens * Retention period of records and specimens	Subpart J Records and Reports * Reporting of nonclinical laboratory study results * Storage and retrieval of records and data * Retention of records	9.Reporting of Study Results * General * Content of the final report 10.Storage and Retention of Records and Material * Storage and retrieval * Retention	9.Reporting of Study Results *General *Content of final report 10.Storage and Retention of Records and Material *Storage and retrieval *Retention	Subpart J Records and Reports * Reporting on the results of the study * Storage and retrieval of records and specimens * Retention period for records and specimens	Final Report Storage of Data	第八章 * 最終試驗報告 * 紀錄及報告之儲存與追溯
		Subpart K Disqualification of Testing Facilities * Purpose * Grounds for disqualifications * Notice of and opportunity for hearing on proposed disqualification * Final order on disqualification * Actions upon disqualification * Public disclosure of information regarding disqualification * Alternative or additional actions to disqualification * Suspension or termination of a testing facility by a sponsor * Reinstatement of a disqualification testing facility					

*加拿大依據美國之規範，比利時依據ＯＥＣＤ規範。

表2 各國ＧＬＰ之標題及適用範圍

國　別	標　　題	用　　範　　圍
中華民國	藥品非臨床試驗優良操作規範	品非臨床試驗優良操作規範(以下簡稱本規範), 係提供藥品研發評估及藥品查驗登記申請文件中的非臨床試驗應遵循之規範, 以確保各項試驗數據之品質及試驗之完整性與可信度。
日　本	Good Laboratory Practice Standards for Safety Studies on Drugs	URPOSE: This Standard prescribes good laboratory practices for nonclinical laboratory studies on safety that are conduced to support application for approvals to manufacture (or import) permits of drugs, reevaluation of new drugs, etc., under the provisions of Article 18-3 Paragraph 2 of the Enforcement Regulations of the Pharmaceutical Affairs Law (Ministry of Health and Welfare Ordinance No.1, 1961: thereinafter referred to as “the regulation”; including cases if application, with necessary modifications, in Article 21-3 Paragraph 2, and Article 21-5 Paragraph 2 of the Regulations). This Standard shall assure the reliability of these safety data..
美　國	Good Laboratory Practice for Nonclinical Laboratory Studies	COPE: This part prescribes good laboratory practices for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for product regulated by the Food and Drug Administration, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products. Compliance with this part is intend to assure he quality and integrity of the safety data filed pursuant to section 406,408,409, 502,503,505,506, 510, 512-516,518-520,721, and 801 of Federal Food, Drug, and Cosmetic Act and section 351 and 354-360F of Public Health Service Act.
OECD	OECD Principles of Good Laboratory Practice: Decision of the Council Concerning Mutual Acceptance of Data in the Assessment of Chemicals	COPE: These Principles of good laboratory practices should be applied to the non-clinical safety testing of test item contained in pharmaceutical products, pesticide products, cosmetic products, veterinary drugs as well as food additives, feed additives, and industrial chemicals. These test items are frequently synthetic chemicals, but may be of natural or biological origin and, in some circumstances, may be living organisms. The purpose of testing these test items is to obtain data on their properties and/or their safety with respect to human health and/or the environment. Non-clinical health and environmental safety studies covered by the principles of good laboratory practice include work conducted in the laboratory, in greenhouses, and in the fields. nless specifically exempted by national legislation, these principles of good laboratory practice apply to all non-clinical health and environmental safety studies required by regulation for the purpose of registering or

		licensing pharmaceuticals, pesticides, food and feed additives, cosmetic products, veterinary drug products and similar products, and for the regulation of industrial chemicals.

表2 各國ＧＬＰ之標題及適用範圍 (續前頁)

國　別	標　　題	適　　用　　範　　圍
法　國	Principles of Good Laboratory Practice for Experimental Toxicology Studies	COPE: This document sets forth principles of Good Laboratory Practice intended to assure the quality and the integrity of the results obtained during experimental toxicity studies undertaken to evaluate the safety of drugs for human or veterinary use. The only studied concerned by these principles are those performed with a view to the constitution of the dossier for Drug Registration (Marketing Authorization). These Good Laboratory Practices do not apply to field studies.
瑞　士	Guide for Good Laboratory Practice Concerning Nonclinical Laboratory Studies	COPE: This guide is applicable to all nonclinical experimental studies which are carried out with test substance regulated by the "IKS-Regulative", and the results of which are to be submitted to an authority with regard to the harmlessners and the compatibility of the substance studies.
英　國	The Principles of Good Laboratory Practice	TRODUCTION: The application of GLP to studies assures the quality and the integrity of the data generated and allows its use by Government Regulatory Authorities in hazard and risk assessments of chemicals.
NLFD	優良實驗操作規範	政院衛生署藥物食品檢驗局，為提高所執行之藥物、食品及化妝品等各項試驗數據之品質及確保試驗之完整、安全性，特訂定優良實驗操作規範。

表3 各國ＧＬＰ定義專有名詞之比較

專　有　名　詞	中華民國	日本	美國	OECD	法國	瑞士	英國	NLFD
Nonclinical Laboratory Study (or Study)	V	V	V	V	V	V		V
Test Article (or Test Substance)	V	V	V	V	V	V	V	V
Control Article (or Control Substance, Reference Substance)	V	V	V	V	V	V	V	V
Lot (or Batch)	V	V	V	V	V	V	V	
Test System	V	V	V	V	V	V	V	V
Specimen	V	V	V	V	V	V		V
Raw Data	V	V	V	V	V	V	V	V
Test Facility	V	V	V	V	V	V	V	V
Quality Assurance Unit (or Quality Assurance Programme)	V	V	V	V	V	V	V	V
Sponsor	V	V	V	V	V	V	V	
Study Director	V	V	V	V	V	V	V	V
Principle Investigator				V				
Management	V	V		V				V
Good Laboratory Practice (GLP)	V			V	V		V	
Standard Operating Procedures (SOPs)				V			V	
Protocol (Study plan)				V	V		V	
Vehicle (Carrier)	V			V	V			
Sample	V			V	V			
IKS-Regulative						V		
Act			V					
Application for Research or Marketing Permit			V					
Personnel			V	V				
Computer Program							V	
Study Initiation Date			V	V				
Study Completion Date			V	V				

Reagent and Solution	V							V
Master Schedule				V				

表4 各國ＧＬＰ試驗機構負責人職責之比較

試驗機構負責人 職責	中華民國	日本	美國	OECD	法國	瑞士	英國	NLFD
確保試驗機構依照GLP執行	V			V	V		V	V
指定試驗主持人	V	V	V	V	V	V	V	V
更換試驗主持人，並作成書面紀錄	V	V	V	V	V	V	V	V
制訂實驗安全措施	V							V
設立品質保證單位	V	V	V	V	V	V	V	V
確保試驗物質、對照物質或其混合物之品質	V	V	V			V		V
確人員等依既定試驗計畫書執行	V	V	V	V	V	V	V	V
確保人員、設施設備及資材供試驗執行	V	V		V	V		V	V
確保依標準操作程序執行	V	V		V	V			V
安全及衛生符合國家有關法令	V			V	V		V	V
確保試驗人員明瞭其執行之工作	V	V	V	V	V	V	V	V
確保試驗執行與GLP偏差時，QA應通知試驗主持人採取措施並記錄	V	V	V		V	V		V
必要時與試驗委託者共同同意試驗計畫書	V							
保存試驗計畫書及有關之標準操作程序及其制定歷程檔案	V			V	V			V
試驗計劃書之修訂確經同意並記錄	V			V	V			V
指定人員負責管理檔案室	V			V	V			
保存人員學經歷、職責及訓練紀錄				V	V		V	
制訂標準操作程序				V	V			
確保試驗紀錄						V		

為試驗主持人之職責

試驗機構應準備與保存

Storage and retrieval of records and specimens (日本GLP Article 28-2；美國GLP 21 CRF 58.190 (c))

表5 各國ＧＬＰ試驗主持人職責之比較

試驗主持人職責	中華民國	日本	美國	OECD	法國	瑞士	英國	NLFD
負責試驗之執行、管制及試驗結果之解釋、分析、紀錄與報告	V	V	V	V	V	V	V	V
試驗計畫書及其變更事項之審核	V	V	V	V	V		V	V
所有試驗數據之記錄與審核	V	V	V	V	V		V	V
記錄影響試驗品質及完整性之突發狀況及措施	V	V	V		V			V
試驗體系符合試驗計畫書	V	V	V					V
試驗程序依GLP執行	V	V	V	V	V			V
原始數據、紀錄、試驗計畫書、標本及總結試驗報告之歸檔	V	V	V	V	V		V	V
同意試驗計畫書			V	V	V		V	
總結試驗報告簽名加註日期並註明負責認可數據之真實性及遵照GLP	V			V	V			V
確保試驗物質、對照物質或其混合物之品質					V			

為試驗機構負責人之職責

表6 各國ＧＬＰ品質保證單位職責之比較

品質保證單位職責	中華民國	日本	美國	OECD	法國	瑞士	英國	NLFD
負責稽查試驗計畫之執行過程符合GLP	V	V	V	V	V	V	V	V
QA人員應熟悉該試驗並由不參與該試驗人員擔任	V	V	V	V	V	V	V	V
保管試驗機構所有進行試驗之主計畫進度表	V	V	V		V			
保存一份負責稽查之試驗其試驗計畫書	V	V	V					V
定期稽查以確保試驗之可信度及完整性	V	V	V	V	V	V	V	V
確定試驗執行與標準操作程序或試驗計畫書有無偏差	V	V	V	V	V		V	V
製作、簽署及保存稽查報告	V							
定期提出稽查試驗之現階段書面報告，簽具問題及措施	V	V	V			V	V	V
影響試驗完整性之重要問題，應報告試驗主持人及試驗機構負責人	V	V	V			V	V	V
稽查總結試驗報告時確定其試驗方法及結果反映試驗之原始數據	V	V	V	V	V	V	V	V
稽查終了簽署報告併於總結試驗報告送試驗主持人及試驗機構負責人	V	V	V	V	V	V	V	V
保存紀錄應含查核日期、試驗名稱、試驗階段及稽查者簽名加註日期	V	V	V	V	V	V	V	V
QA之職責及作業程序與編索應制訂標準操作程序	V	V	V	V		V		V
QA保存之紀錄應存適當場所備查	V	V				V		V
確認參與試驗人員符合試驗計畫書及標準操作程序之要求				V	V			V

表7 各國ＧＬＰ標準操作程序涵蓋事項之比較

標準操作程序事項	中華民國	日本	美國	OECD	法國	瑞士	英國	NLFD
儀器及器具之使用與管理	V	V		V	V			V
機器及設備之使用與管理	V	V	V	V	V	V	V	V
試藥及溶液之管制	V			V	V			V
試驗物質及對照物質之管制	V	V	V	V	V	V	V	V
試驗方法(試驗檢查、分析及測定方法)	V	V	V			V	V	V
動物及動物房之管理	V	V	V	V	V	V		V
實驗動物之鑑定、房舍、配置及運送(含特性及照護)	V	V	V	V	V	V	V	
試驗體系之觀察及調查	V	V	V	V	V	V	V	
瀕死及死亡實驗動物之處理	V	V	V	V	V	V	V	
實驗動物之解剖及死後解剖之檢查	V	V	V	V	V	V	V	
標本之收集、鑑定及管理	V	V	V			V	V	V
組織病理學之檢查	V	V	V	V	V	V	V	
微生物試驗							V	
田野試驗							V	
紀錄與報告之管理	V	V	V	V	V	V	V	V
品質保證工作之執行	V	V		V	V		V	V
試驗安全衛生管制	V	V		V				V
廢棄物處理	V							V
環境管制								V
菌種及培養基之管理								V
危險及放射物質管制								V
其他有關事項之管制	V							V

為品質保證單位之職責

表8 各國ＧＬＰ試驗計畫書涵蓋事項之比較

試驗計畫書事項	中華民國	日本	美國	OECD	法國	瑞士	英國	NLFD
試驗名稱、性質及目的	V	V	V	V	V	V	V	V
試驗機構或試驗委託者之名稱及地址	V	V	V	V	V	V	V	V
試驗主持人姓名	V	V		V	V	V		
試驗所需人力	V							V
試驗開始及結束預定日與預定進度	V			V	V	V	V	V
試驗物質及對照物質之識別	V	V	V	V	V	V	V	V
試驗設計之敘述，包括取樣計畫及偏差管制的方法	V	V	V			V	V	V
試驗方法(含執行試驗之調查、分析、測定及觀察之種類與頻率)	V	V		V				
試驗體系選擇理由	V	V		V	V	V	V	V
試驗體系特性如品種、品系、數量、年齡、體重範圍及供應來源等	V	V	V	V	V	V	V	V
試驗體系之識別法	V	V	V			V	V	V
試驗過程所需的溶劑、乳化劑、飼料、飲料等之敘述或鑑別。	V	V	V					
投予途徑及選擇該途徑之理由	V	V		V	V	V	V	V
投予劑量、方法及頻率	V	V	V	V	V	V	V	V
統計方法之敘述	V	V	V	V	V	V	V	V
試驗計畫書核准日期	V	V	V	V	V	V		
試驗主持人簽章及簽註日期	V	V	V	V	V	V	V	V
須保存紀錄與資料之項目	V	V	V	V	V	V	V	V
修訂或變更經計畫主持人核准之簽名及簽註日期，並註明期修訂原因	V							
試驗體系之環境條件		V				V		
試驗體系對試驗物質及對照物質吸收程度之測定方法							V	V

表9 各國ＧＬＰ總結試驗報告涵蓋事項之比較

總結試驗報告之內容	中華民國	日本	美國	OECD	法國	瑞士	英國	NLFD
試驗名稱、性質及目的	V	V	V	V	V		V	V
試驗機構、單位名稱及地址	V	V	V	V	V		V	V
試驗之開始及完成日期	V	V	V	V	V		V	V
試驗方法之依據	V		V	V	V			V
取樣及試驗過程中所產生之完整紀錄	V							V
試驗物質及對照物質之識別	V	V	V	V	V		V	V
試驗物質及對照物質投予條件之安定性	V	V	V				V	V
試驗體系之特性(品種、品系、數量、年齡、體重範圍及供應來源等)	V	V	V				V	V
試驗體系之識別程序	V		V					V
投予劑量、途徑、頻率及投予期間	V	V	V				V	V
試驗主持人姓名及參與試驗人員姓名(及業務分配)	V	V	V		V		V	V
分析數據所用之統計方法及演算公式	V	V	V	V	V	V	V	V
影響數據品質及試驗完整性之因素	V	V	V		V	V		V
試驗數據之運算，分析及其導出之結論與試驗結果之評估判定與摘要	V	V	V	V	V	V	V	V
標本、原始數據及總結試驗報告之儲存場所及期限	V	V	V	V	V	V		V
原始試驗計畫書之任何變更事項	V		V			V		V
品質保證單位之稽查報告	V	V	V	V	V	V	V	V
總結試驗報告撰寫日期		V						
參與試驗之負責研究人員簽章及加註日期	V		V	V	V	V	V	
試驗主持人簽名(及加註日期)	V	V	V	V	V	V	V	V
總結試驗報告之補充或修正及其理由	V	V	V	V	V	V	V	V
有關之資訊與數據，包括核可之試驗計畫書、變更及修正						V		
飼料及媒體之鑑別							V	V
試驗物質及對照物質劑量設計之理由		V						

表10 各國ＧＬＰ紀錄之保存期限

國　別	紀　錄　種　類	保　　存　　期　　限
中華民國	試驗計畫書；標本；樣品；原始數據；紀錄文書；總結試驗報告；試驗人員學經歷及訓練檔案；QA之稽查紀錄；主計畫進度表與試驗計畫書影本；設備稽查、維護及修繕紀錄。	* 經申請中央衛生管機關藥品查驗登記許可後，其保存期間至少五年；其未申請者亦應保存至試驗完成或終止 後至少二年。 * 濕性標本、試驗物質或對照物質樣品及經特別處理之物質等保存過程易顯著變質者，應保存至該物質可評估之最後期限。
日　本	試驗計畫書；標本；原始數據；紀錄文書；總結試驗報告；試驗人員學經歷及訓練檔案；QA之稽查紀錄、主計畫進度表與試驗計畫書本；設備稽查、維護及修繕紀錄。	* Five years after the date of application approval; 5 years after the completion of a reexamination; for drugs that require more than 5 years for reexamination, up to the time the reexamination is completed; for 5 years after the reporting of data used as the grounds for an adverse reaction; for 5 years after a foreign acquire of manufacturing approval reports of data used as the grounds for an adverse reaction. * Wet specimen which differ markedly in quality during storage, shall be retained only as long as the quality of the preparation affords evaluation.
美　國	試驗計畫書；標本；原始數據；紀錄文書；總結試驗報告；試驗人員學經歷及訓練檔案；QA之稽查紀錄、主計畫進度表與試驗計畫書影本；設備稽查、維護及修繕紀錄。	* Two years from the date of application for a research or market permit (not an IND), or 5 years following the date that study was submitted to the FDA in support of an application for a research or marketing permit, or in other situation, 2 years from study completion or termination. * Wet specimen, which differs markedly in quality during storage, shall be retained only as long as the quality of the preparation affords evaluation.
ＯＥＣＤ	試驗計畫書；標本；樣品；原始數據；紀錄文書；總結試驗報告；試驗人員學經歷及訓練檔案；QA之稽查紀錄；設備稽查、維護及修繕紀錄；標準操作程序之制訂歷程。	* As specified by the appropriate authority. * Samples and specimens shall be retained only as the quality of the preparation permits evaluation.
法　國	試驗計畫書；標本；樣品；原始數據；紀錄文書；總結試驗報告；試驗人員學經歷及訓練檔案；QA之稽查紀錄；設備稽查、維護及修繕	* As specified by the appropriate authority. * Samples and specimens shall be retained only as the quality of the preparation permits

	紀錄；標準操作程序之制訂歷程。	evaluation.

表10 各國ＧＬＰ紀錄之保存期限(續前頁)

國　別	紀　錄　種　類	保　　存　　期　　限
瑞　士	試驗計畫書；標本；樣品；原始數據；紀錄文書；總結試驗報告；試驗人員學經歷及訓練檔案；QA之稽查紀錄；設備稽查、維護及修繕紀錄；標準操作程序之制訂歷程；試驗及對照物質。	* At least 5 years. * Samples and specimens shall be retained only as the quality of the preparation permits evaluation.
英　國	試驗計畫書；標本；樣品；原始數據；紀錄文書；總結試驗報告。	* 無規定保存年限
ＮＬＦＤ	試驗計畫書；標本；原始數據；紀錄文書；最終試驗報告；試驗人員學經歷及訓練檔案；QA之查核紀錄、主計畫進度表與試驗計畫書影；設備查核、維護及修繕紀錄。	
		* 保存年限依規定

附件Ⅰ、規範中英條文對照表

藥品非臨床試驗優良操作規範

第壹章　總則

一、

藥品非臨床試驗優良操作規範(以下簡稱本規範)，係提供藥品研發評估及藥品查驗登記申請文件中的非臨床試驗應遵循之規範，以確保各項試驗數據之品質及試驗之完整性與可信度。

二、本規範專有名詞之定義如下：

(一)實驗室優良操作規範 (Good laboratory practice, GLP)
實驗室優良操作規範係指有關實驗室試驗之計畫、執行、監測、記錄、報告及檔案的組織架構及規範。

(二)非臨床試驗 (Nonclinical laboratory study)
非臨床試驗(以下簡稱試驗)係指於實驗室條件下之試驗體系，用活體內或活體外試驗來測試試驗物質的安全性。此試驗並不包括人體試驗或臨床試驗，亦不包括測試試驗物質是否具有任何潛在用途或針對其物理或化學性質所作的基礎性研究。

Good Laboratory practices for Nonclinical Laboratory Studies

Chapter 1 General Provisions

1.1 This Standard prescribes good laboratory practices for nonclinical laboratory studies (hereinafter abbreviated as "Standard") on safety that are conducted to support applications for research and marketing permits of new drug regulated by the national authority. This Standard shall assure the reliability of these safety data. (FDA 58.1;JP 1)

1.2 Definitions

The major terms used in this Standard shall have following meanings.

1."Good laboratory practices (GLP)" is a quality system concerned with the organizational process and the conditions under which nonclinical laboratory studies are planned, performed, monitored, recorded, archived and reported. (OECD2.1)

2."Nonclinical laboratory study" means any *in vivo* or *in vitro* experiments in which test articles are studied prospectively in test systems under laboratory conditions to determine their safety. The term dose not include studies utilizing human subjects or clinical studies. The term does not include basic exploratory studies carried out to determine whether a test article has any potential utility or to determine physical or chemical characteristics of a test article. The term is hereinafter abbreviated as "study". (FDA 58.3(d))

(三)試驗機構 (Testing facility) 試驗機構係指包括執行試驗所需之人員、設施、設備及作業部門。	3."Test facility" means the persons, premises, and operational unit(s) that are necessary for conducting the study. (OECD 2.2(1))
(四)試驗機構負責人 (Management) 試驗機構負責人係指管理該試驗機構整體作業之負責人。	4."Management" means a person responsible for the overall operation of a testing facility. (JP 2-10)
(五)試驗主持人 (Study director) 試驗主持人係指執行該試驗之負責人。	5."Study director" means the individual responsible for the overall conduct of the study. (FDA 58.3(m);JP 2-11)
(六)試驗委託者 (Sponsor) 試驗委託者係指提供試驗之財務或其他資源；或將試驗結果向中央衛生主管機關申請藥品查驗登記之個人或法人，亦可為執行試驗之試驗機構。	6."Sponsor" means a person who commissions a study by provision of financial or other resources, or who submits results of a study to the national authority, or a testing facility, if it both initiates and actually conducts the study. (FDA 58.3(f);JP 2-9)
(七)品質保證單位 (Quality assurance unit) 品質保證單位係指為確保試驗符合本規範之規定，由試驗機構負責人指定執行品質保證工作且未參與此研究之人員或組織。	7."Quality assurance unit" means any person or organization designated by the management in order to perform duties guaranteeing that study conducted at a testing facility is in accordance with this Standard, among persons who do not participate in that study. (JP 2-12)
(八)試驗體系 (Test system) 試驗體系係指試驗中所用來測試試驗物質或對照物質之動物、植物、微生物、細胞或其組成部份，化學或物理等體系或其合併體系。	8."Test system" means any animal, plant, microorganisms, as well as other cellular, sub-cellular, chemical, or physical system or a combination thereof to which the test or control article is administered or added for study. (FDA 58.3(i);OECD 2.3(6))
(九)試藥與溶液 (Reagents and solutions) 試藥與溶液係包括試藥、試液、溶劑、指示劑、試紙、比色溶液及容量分析溶液等。	9."Reagents and solutions include reagents, test solutions, solvents, indicators and volumetric analysis solutions etc. (NLFD)

(十)試驗物質 (Test article)
試試驗物質係指任何待測之藥品、化學、生物物質或其混合物。

10."Test article" means any drug, chemical or biological substance, or mixture of substances thereof to be studied. (JP 2-2)

(十一)對照物質 (Control article or Reference article)
對照物質係指於試驗期間，用以與試驗物質比較之藥品、化學、生物物質及其混合物。

11."Control article (or Reference article)" means any drug, chemical or biological substance or mixture of substances thereof to be studies for the purpose of comparison with the test article. (JP 2-3)

(十二)賦形體 (Vehicle or Carrier)
賦形體係指用來混合、分散或溶解以利於試驗物質或對照物質投予試驗體系之媒介物質。

12."Vehicle (or Carrier) means any agent which serves as a carrier used to mix, disperse, or solubilize the test or reference article to facilitate the administration to the test system. (OECD 2.4(4))

(十三)批 (Lot (or Batch))
批係指如本規範第陸章第一項所述之特定數量之試驗物質或對照物質，其具有均一之特性與品質。

13."Lot (or Batch)" means a specific quantity of a test or control article that has been characterized according to paragraph 6.1 and with uniformity. (FDA 58.3(n);JP 2-4)

(十四)樣品 (Sample)
樣品係指定量之試驗物質或對照物質。

14."Sample" means any quantity of the test or control article.

(十五)標本 (Specimen)
標本係指由試驗體系衍生而來用於檢查或分析之物質。

15."Specimen" means any material derived from a test system for examination or analysis. (FDA 58.3(j))

(十六)原始數據 (Raw data)
原始數據係指於試驗過程中為整理或評估試驗報告所需保留之任何觀察結果、原始紀錄、文件或其精確複印本。原始數據可包括相片、微縮影片、電腦列印報表、磁性媒體及自動裝置等所得到之觀察數據或其紀錄。

16."Raw data" means worksheets, notes, memoranda, or exact transcripts thereof, etc. which record original observations and activities in a study and are necessary for the reconstruction and evaluation of the report of that study. Raw data may include photographs, microfilm, computer printouts, magic records, and data recorded by automatic instruments, etc. (JP 2(7))

三、試驗委託者對受託試驗機構之通知

試驗委託者申請受託試驗機構進行試驗時，試驗委託者必須事先通知受託試驗機構遵照本規範進行試驗。

1.3 Notification to a contract laboratory by a sponsor

When a sponsor commissions a contract laboratory to conduct a study under application of this Standard, he shall notify the contract laboratory facility in advance that the study must be conducted in compliance with the provisions in this Standard. (FDA 58.10;JP 3)

四、查核

(一)中央衛生主管機關為確認試驗之可信度及完整性，試驗機構應允許其查核人員隨時查核依本規範之設施及保存之文書紀錄、標本等；查核人員得影印或以其他適當方法複製該文書紀錄或其副本。

(二)前款所述之查核，必要時中央衛生主管機關得指定適當人員查核；或邀請有關機關或專家參加查核。

1.4 Inspections

1. A testing facility shall permit inspections into its facilities or into records, specimens etc. (and in the case of records also to copy) required to be maintained regarding a study under this Standard, when the national authority orders such inspections in order to assure the reliability of a study. ((JP 4-1)

2.The inspection mentioned in the section 1.4 paragraph 1 shall be performed by officials in charge in the national authority or by those who are designated by the national authority.

(JP 4-2)

第貳章　組織與人事

Chapter 2 Organization and Personnel

一、組織

試驗機構內置試驗機構負責人負責整體試驗之管理，且每一試驗計畫應有一試驗主持人負責試驗之執行，並應設品質保證單位稽查各項試驗工作以確保其執行過程均符合本規範之要求。

2.1 Organization

There shall be a testing facility management for the overall operation of testing facility. A study director is designated for each study responsible for the conduct of the study. Quality assurance unit is designated to perform duties to assure that the study conducted is in accordance with this Standard. (NLFD)

二、人員管理

(一)參與執行的每一位人員及負有監督責任者必須具備相當之教育、訓練、經驗或兼具而能勝任其職務。

2.2 Personnel

1.Each individual engaged in the conduct of or responsible for the supervision of a study shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions. (FDA 58.29(a))

(二)應以書面制訂試驗機構內每一職位之工作職責，並應確實遵行之。

2.The job and duty of each individual in testing facility shall be set forth in writing and actually followed. (NLFD)

(三)應保存實際參與試驗者之學歷背景、經歷、曾接受有關訓練及工作職責等之最新資料。

3.Each testing facility shall maintain a current summary of training and experience and job description for each individual engaged in or Supervising the conduct of a study. (FDA58.29(b);JP5-5;OECD1.1(b); SW B.2(b);UK4(e);NLFD)

(四)應依據試驗計畫書之要求，提供足夠之人員參與試驗工作。

4.A sufficient number of personnel shall be available in a testing facility for the timely and proper conduct of a study according to the protocol. (FDA 58.29(c))

(五)應制訂新進及在職人員應有之訓練程序，以確保每一位試驗人員均能勝任其職務，且應將訓練內容及結果作成完整之紀錄。

5.Training procedures for personnel shall be established to assure that each individual being capable of performing their duties. The description and result of the training procedure shall be completely recorded. (NLFD)

(六)試驗操作人員應注意個人衛生及健康，以防止污染試驗物質、對照物質及試驗體系等。

6.Personnel shall take necessary personal sanitation and health precautions designed to avoid contamination of test and control articles and test systems. (FDA 58.29(d))

(七)參與試驗者發現罹患足以影響試驗可信度之疾病應報告其監督者，應避免參與試驗，與試驗物質、對照物質及試驗體系接觸，以免影響試驗品質及其完整性，直至其恢復健康狀況。	7.Any individual found at any time to have an illness that may adversely affect the quality and integrity of the study shall be excluded from direct contact with test systems, test and control articles and any other operation or function that may adversely affect the study until the condition is corrected. All personnel shall be instructed to report to their immediate supervisors any health or medical conditions that may reasonably be considered to have an adverse effect on a study. (FDA 58.29(f))
(八)參與試驗者應配合工作性質穿著適當之工作衣物(包括護鏡、保護衣、口罩、手套、鞋、襪等)執行工作，並依需要經常換洗，以防止來自試驗物質、對照物質及試驗體系之微生物、放射性物質或化學性物質等之污染。	8.Personnel engaged in a study shall wear clothing appropriate for the duties they perform. Such clothing shall be changed as often as necessary to prevent microbiological, radiological, or chemical contamination of test systems and test and control articles. (FDA 58.29(e))
(九)試驗人員應配合工作性質接受定期健康檢查。	9.Personnel engaged in a study shall take routine health examination in accordance with the duties they perform. (NLFD)
(十)試驗人員必須遵守實驗室安全及其有關規定執行試驗。	10.Personnel should exercise safe working practice.
三、試驗機構負責人 試驗機構負責人應確保試驗機構依照本規範執行，並確保下列事項：	**2.3 Testing facility management** Testing facility management should ensure that the Standard are complied with in the testing facility. The management shall undertaken the following. (OECD 1.1(1))

(一)確保每一試驗開始前均有一指定如本章第四項所述之試驗主持人負責該試驗之執行。	1.Designate a study director as described in Section 8.4 in this chapter, before the study is initiated. (FDA 58.31(a))
(二)於試驗過程中視需要可即時更換試驗主持人，惟其更換事宜應作成書面紀錄。	2.Replace the study director promptly if it becomes necessary to do so during the conduct of the study, record this in writing. (FDA 58.31(b); JP 6-2)
(三)制訂實驗安全措施以確保實驗室安全。	3.Safety precaution procedures shall be set forth to assure laboratory safety. (NLFD)
(四)設立如本章第五項所述之品質保證單位，並確保其功能符合本規範之規定。	4.Assure that there is a quality assurance unit as described in paragraph 2.5. (FDA 58.31(c))
(五)確保試驗物質、對照物質或其混合物於必要時進行適當之鑑別，並測試其含量、純度、安定性及均一性等試驗。	5.Assure that test and control articles or mixtures have been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable. (FDA 58.31(d))
(六)確保人員、試驗材料、經費、設施、儀器、設備及試驗方法均依既定計畫執行之。	6.Assure the personnel, resources, facilities, equipment, materials, and methodologies are available as scheduled. (FDA 58.31(e))
(七)確保每一試驗均依既定之標準操作程序執行，而其安全及衛生規定皆符合國家有關法令之要求。	7.Assure that appropriate standard operating procedures are established and followed; assure that health and safety precautions are applied according to national and/or international regulations. (OECD 1.1-2(e))
(八)確保試驗人員都確切明瞭其執行之工作。	8.Assure that personnel clearly understand the function they are to perform. (FDA 58.31(f))

(九)確保當試驗執行與本規範有所偏差時，品質保證單位應通知試驗主持人採取改善補救措施並作成書面紀錄。

9.Assure that any deviations from this Standard reported by the quality assurance unit are communicated to the study director and corrective action are taken and documented. (FDA 58.31(g);JP 6(7))

(十)必要時與試驗委託者共同同意試驗計畫書。

10.Where appropriate, agree to the study protocol in conjunction with the sponsor.

(十一)確保試驗計畫書、有關之標準操作程序及其制訂歷程檔案均妥善保存。

11.Maintain copies of all study protocols and a historical file of all standard operating procedures. (OECD 1.1(2-i,k))

(十二)確保試驗計畫書之修訂確經同意並予以詳確記錄。

12.Assure that amendments to the study protocol are agreed upon and documented. (OECD 1.1(2-i))

(十三)應指定一位經授權之人員負責管理檔案室。

13.Assure that an individual is identified as responsible for the management of the archives. (OECD 1.1(2-l))

四、試驗主持人

試驗主持人應由具備相當教育、訓練、經驗或兼具之科技專業人員擔任。試驗主持人對試驗之執行及管制，試驗結果之解釋、分析、紀錄及報告等負整體之責任並應確保下列事宜：

2.4 Study director

For each study, a scientist or other professional of appropriate education, training, and experience, or combination thereof, shall be identified as the study director. The study director has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation and reporting of results, and represents the single point of study control. The study director shall assure that: (FDA 58.33)

(一)試驗計畫書及其任何變更事項，均依照本規範第七章之規定審核後執行。

1.The protocol, including any change, is approved as provided by chapter 7 and is followed.
(FDA 58.33(a))

(二)所有試驗數據包括試驗體系中非預期之觀察結果，均經詳確記錄及審核。	2.All experimental data, including observations of unanticipated responses of the test system are accurately recorded and verified. (FDA 58.33(b))
(三)試驗過程中，足以影響試驗品質及其完整性之突發狀況與所採取之補救措施，均經詳確記錄。	3.Unforeseen circumstances that may affect the quality and integrity of the study are noted when they occur, and corrective action is taken and documented. (FDA 53.33(c))
(四)所使用之試驗體系符合試驗計畫書之規定。	4.Test systems are as specified in the protocol. (FDA 58.33(d))
(五)試驗程序均依本規範規定執行。	5.All applicable good laboratory practice regulations are followed. (FDA 58.33(e))
(六)所有原始數據、紀錄、試驗計畫書、標本及總結試驗報告等，於試驗過程或試驗終了均予以歸檔。	6.All raw data, documentation, protocols, specimens and final reports are transferred to the archives during or at the close of the study. (FDA 58.33(f))
五、品質保證單位	**2.5 Quality assurance unit**
(一)試驗機構應設品質保證單位，負責稽查試驗計畫之執行過程，以確保其設施、設備、儀器、人員、試驗方法、各項管制及紀錄等符合本規範之要求。	1.A testing facility shall have a quality assurance unit which shall be responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, record, and controls are in conformance with this standard. (FDA 58.35(a))

(二)執行品質保證工作人員應熟悉該試驗且經有關訓練並由不參與該試驗之人員擔任。

2.The individual(s) designated for each study in the quality assurance unit shall be a person who is familiar with the test procedure and does not participate in the study. (JP 8(1);OECD 2.1(2,3))

(三)品質保證單位之職責及作業程序：

1.負責保存一份在試驗機構裏所有進行試驗之主計畫進度表(依試驗物質製作索引)，內容包括試驗物質或成分、試驗體系、試驗性質、試驗執行日期、各試驗階段、試驗委託者姓名、試驗主持人姓名及總結試驗報告。

3.Responsibilities and operating procedures of quality assurance unit:

(1) Maintain a copy of a master schedule sheet (or a document indexed by test article and containing the test system, nature of study, date on which the study was initiated, current status of each study, name of the sponsor, name of the study director, and status of the final report) of all studies conducted at the testing facility. (JP 8-2(1))

2.對負責稽查之試驗應保存一份其試驗計畫書。

(2) Maintain copies of all protocols pertaining to all studies for which the unit is responsible. (FDA 58.35(b)(2))

3.定期稽查各試驗階段以確保所執行之試驗符合試驗計畫書及標準操作程序，將稽查試驗結果及內容、稽查所發現問題之缺失及改進措施與再稽查日期等製作成報告並簽署後保存。試驗階段應於適當的間隔定期稽查，以確保試驗之可信度及完整性。稽查過程中如發現影響試驗可信度及完整性之重要問題時，應立刻報告試驗主持人及試驗機構負責人。

(3) Inspect each study at intervals adequate to insure the integrity of the study and maintain written and properly signed records of each periodic inspection showing the date of the inspection, the study inspected, the phase or segment of study inspected, the person performing the inspection, finding and problems, action recommended and taken to resolve existing problems and any scheduled date for re-inspection. Any problems found during the course of an inspection which are likely to affect the study integrity shall be brought to the attention of the study director and management immediately. (FDA 58.35(b)(3))

4.應對負責稽查之試驗定期提出稽查試驗之現階段書面報告，簽具問題缺失並提具體修正措施，並送交試驗機構負責人及試驗主持人。

(4) Periodically submit to management and the study director written status reports on each study, noting any problems and the corrective actions taken. (FDA 58.35(b)(4))

5.應確定所稽查之試驗其執行與標準操作程序或核准之試驗計畫書無未經審核之任何偏差發生。

(5) Determine that no deviations from approved protocols or standard operating procedures were made without proper authorization and documentation. (FDA 58.35(b)(5))

6.稽查總結試驗報告時應確定該報告正確地記載試驗方法，且其結果正確反映試驗之原始數據。

(6) Review the final study report to assure that such report accurately describes the methods, and that the reported results accurately reflect the raw data of the study. (FDA 58.35(b)(6))

7.稽查終了應簽署一份報告併於總結試驗報告送交試驗主持人及試驗機構負責人，該報告應載明稽查日期及於稽查過程中所發現之缺失及改進措施。

(7) Prepare and sign a statement to be included with the final study report which shall specify the dates inspections were made and finding reported to management and to the study director. (FDA 58.35(b)(7))

(四)品質保證單位之職責及其作業程序以及編索有關紀錄的方法均應制訂標準操作程序並保存遵行之。所有保存之紀錄應包括稽查日期、試驗名稱、試驗階段及稽查者之簽名、簽註日期。

4.The responsibilities and procedures applicable to the quality assurance unit, the records maintained by the quality assurance unit, and the method of indexing such record shall be in writing and shall be maintained. These items including inspection dates, the study inspected, the phase segment of the study inspected, and the name of the individual performing the inspection. (FDA 58.35(c))

(五)所有品質保證單位保存之紀錄應存放於試驗機構備查。

5.All records maintained by the quality assurance unit shall be kept in the testing facility for inspection. (JP 8-4)

第參章　設施

Chapter 3 Facilities

一、一般規定

試驗機構應有適當之配置、空間及構造以利試驗之執行，且其設計須有適當程度之隔離，以避免任何功能或活動對試驗產生不良的影響。

3.1 General

Each testing facility shall be of suitable size and construction to facilitate the proper conduct of the study. It shall be designed so that there is a degree of separation that will prevent any function or activity from having an adverse effect on the study. (FDA 58.41)

二、動物管理設施

(一)動物管理設施之設計、構造及配置應以對試驗之干擾降至最低為原則。

3.2 Animal care facilities

1.A testing facility shall have a animal care facilities of appropriate design, construction and suitably located to minimize interference with the purpose of the study.

(二)為確保動物品種(系)或試驗體系之區分、個別計畫之獨立、動物檢疫之隔離、一般或特定動物之飼養，必要時應設足夠的動物飼養場所。

2.A testing facilities shall have a sufficient number of animal rooms or areas, as needed, to assure proper: separation of species or test system, isolation of individual projects, quarantine of animals, and routine or specialized housing of animals. (FDA 58.43(a))

(三)當使用之試驗體系或試驗物質及對照物質具有生物危險性(包括揮發性、放射性、傳染性物質及噴霧劑等)時，應具足夠之動物飼養場所以供與前款之場所分開。

3.A testing facility shall have a number of animals rooms or areas separate from those described in the preceding paragraph to ensure isolation of studies being done with test systems or test and control articles known to be biohazardous, including volatile substances, aerosols, radioactive materials, and infectious agents. (FDA 58.43(b))

(四)應提供適當的場所作為診療及控制試驗動物疾病之用，且應提供已知或疑似染有疾病之動物、帶菌者與其他動物作有效隔離的場所。

4.Separate areas shall be provided, as appropriate, for the diagnosis, treatment, and control of laboratory animal diseases. These areas shall provide effective isolation for the housing of animals either known or suspected of being diseased, or being carriers of disease, from other animals. ((FDA 58.43(c))

(五)動物飼養場所應有收集及衛生處理試驗體系所產生之排泄物、廢棄物之設施，若無前述設施則於運出試驗機構前應予安全且衛生之儲存。該處理設施應具有將疾病、氣味、害蟲孳生和環境污染降至最低之功能。

5.When animals are housed, facilities shall exist for the collection and disposal of all animal waste and refuse or for safe sanitary storage of waste before removal from the testing facility. Disposal facilities shall be so provided and operated as to minimize vermin infestation, odors, disease hazards, and environmental contamination. (FDA 58.43(d))

三、動物用品供給設施

試驗機構內必要時應具備儲存飼料、床敷、墊料、飼養用品及器具之場所，且飼料、床敷及墊料的儲存場所與試驗體系之飼養場所分開，以防止污染。易腐爛之用品或飼料應以適當方法儲存之。

3.3 Animal supply facilities

There shall be storage areas, as needed, for feed, bedding, supplies, and equipment. Storage areas for feed and bedding shall be separated from areas housing the test systems and shall be protected against infestation or contamination. Perishable supplies shall be preserved by appropriate means. (FDA 58.45)

四、試驗物質及對照物質之管理設施

(一)為防止污染及混淆，試驗機構應有下列區域：

1.試驗物質及對照物質之驗收、儲存及處理場所。

2.試驗物質、對照物質與賦形體之調和場所。

3.前述混合物之儲存場所。

3.4 Facilities for handing test and control articles

1.As necessary to prevent contamination or mix-up, there shall be areas for:

(1) Receipt and storage of the test and control articles.

(2) Mixing of the test and control articles with a carrier.

(3) Storage of the test and control articles mixtures. (FDA 58.47(a))

(二)前款所列工作區域應與試驗體系之飼養場所隔離，並確保試驗物質或對照物質及其混合物之力價 純度 均一性及安定性。

2.The area specified in the preceding paragraph shall be separate from areas housing the test systems and shall be adequate to preserve the identity, strength, purity, and stability of the articles and mixtures. (FDA 58.47(b))

五、試驗操作區域
試驗機構應具有足敷試驗所需之設施, 且應視需要提供適當之隔離試驗場所, 以執行所需之例行工作及特定工作, 其試驗場所之設置條件應配合工作之需要。

3.5 Laborat
Separate laboratory space shall be provided, as needed, for the performance of the routine and specialized procedures required by the studies. (FDA 58.49)

六、標本、紀錄與報告之管理設施
應提供存放與檢索所有試驗計畫書、原始數據、標本、樣品、文書紀錄與報告之場所, 此場所非經授權不可進入。

3.6 Specimen and data storage facilities
Space shall be provided for archives, limited to access by authorized personnel only, for the storage and retrieval of all raw data and specimens from completed studies. (FDA 58.51)

七、實驗室安全及廢棄物處理設施
實驗室之安全防護及廢棄物之處理應符合法令規章。

3.7 Laboratory safety and waste disposal facilities
Safety precautions and waste disposal facilities are to be established according to national legislation or guidelines. (NLFD)

第肆章 設備

Chapter 4 Equipment

一、一般規定

4.1 General

(一)用於數據之產生、處理及評估之儀器或器具以及環境管制所需之機器, 應具有適當的設計及足夠功能, 且其配置應便於操作、檢查、清潔與維護。

1.Equipment used in the generation, measurement, or assessment of data and equipment used for facility environmental control shall be of appropriate design and adequate capacity to function according to the protocol and shall be suitably located for operation, inspection, cleaning, and maintenance. (FDA 58.61)

(二)有關物理、化學及生物等各項試驗, 應視其需要設置所需之設備, 且其設置之條件應能配合工作需要, 並妥為配置及維護

2.Equipment used for the generation of physical, cheminal and biological data should be suitably located and of appropriate design and adeqate capacity. (OECD 5.1(1))

(三)用於試驗之儀器及器材選擇以對試驗體系或試驗目的之干擾降至最低為原則。	3.Apparatus and materials used in studies should be chosen as to minimize interference with the test system and the purpose of the study. (FR 4.2)
二、維護與校正	**4.2 Maintenance and calibration of equipment**
(一)用於數據之產生、處理或評估之設備應予適當之清潔、定期維護及校正。	1.Equipment shall be adequately inspected, cleaned, and maintained. Equipment used for the generation, measurement, or assessment of data shall be adequately tested, calibrated and /or standardized. (FDA 58.63(a))
(二)應制訂有關操作、稽查、校正及維護儀器、器具、裝置、儀表及記錄器等之標準操作程序, 明確規定其校正、維護方法及頻率。標準操作程序中對前述各項工作應指定專人負責。	2.There shall be standard operating procedures setting forth in sufficient detail the methods, materials, and schedule to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation. (FDA 58.63(b))
(三)前款設備經校正，若發現未能符合其精確度界限，應限制使用並採取補救措施。	3.The equipment specified in the preceding paragraph shall be specifying remedial actions to be taken in the event of failure or malfunction of equipment. (FDA 58.63(b))

(四)所有儀器操作、稽查、維護及校正紀錄均應予保存，前述紀錄應含各項工作之日期，並註明其操作維護是否依照既定之標準操作程序進行。若因儀器功能失常所執行之非例行性修護工作，其紀錄應記載該缺點發生時間、原因以及所採取之補救措施。

4.Written records shall be maintained of all inspection, maintenance, testing, calibrating and/or standardizing operations. These records, containing the data of operation, shall describe whether the maintenance operations were routine and followed the writteen standard operating procedures. Written records shall be kept of nonroutine repairs performed on equipment as a result of failure and malfunction. Such records shall document the nature of the defect, how and when the defect was discovered, and any remedial action taken in response to the defect. (FDA 58.63(c))

第伍章　試驗機構之操作

Chapter 5 Testing Facilities Operation

一、標準操作程序

5.1 Standard operating procedures

(一)為提高試驗數據之品質及確保試驗之完整、安全性，應依本規範制訂各項標準操作程序，並經試驗機構負責人審核後實施。

1.A testing facility shall have standard operating procedures in writing and approved by management that set forth concretely th study methods and procedures that are adequate and appropriate to ensure the quality and integrity of the data generated in the course of a study. (FDA 58.81(a))

(二)標準操作程序應存放於各有關之試驗場所。其他發表之文獻、書籍或實驗手冊等可作為標準操作程序之補遺。

2.Each laboratory area shall have immediately available laboratory manuals and standard operating procedures relative to the laboratory procedures being performed. Published literature may be used as a supplement to standard operating procedures. (FDA 53.81(c))

(三)試驗中各項操作與既定之標準操作程序有所偏差時應予記錄，並由試驗主持人作合理的判釋。重大的變更則必須經試驗機構負責人審核，並保存書面紀錄。

3.All deviations in a study from standard operating procedures shall be authorized by the study director and shall be documentted in the raw data. Significant changes in established standard operating procedures shall be properly authorized in writing by management. (FDA 58.81(a))

(四)標準操作程序修訂時，均應經試驗機構負責人核准。有關標準操作程序之制訂歷程及修訂版應予保留。

4.A historical file of standard operating procedures, and all revisions thereof, including the dates of such revisions, shall be maintained. (FDA 58.81(d))

(五)標準操作程序原則上需涵蓋下列各款有關項目：

1.儀器及器具之使用與管理。

5.Standard operating procedures shall be established for the following items, in principle.

(1) Use, maintenance, cleaning, calibration of apparatus. (OECD 7.4-2(a))

2.機器及設備之使用與管理。

(2) Maintenance and repair of facilities and equipmenet. (JP 19-2(3))

3.試藥及溶液之管制。

(3) Preparation and labeling of materials, reagents and solutions. (OECD 7.4-2(b))

4.試驗物質及對照物質之管制。

(4) Receipt , identification, storage, handing, mixing and method of sampling of the test and control articles. (FDA 58.81(b)(3)

5.試驗方法。

(5) Methods of measurements, laboratory tests, and analyses. (FDA 58.81(b)(5); JP19-2(6))

6.動物及動物房之管理。

(6) Animal care and animal room preparation. (FDA 58.81(b)(1),(2); JP19-2(2))

7.實驗動物之鑑定、房舍、配置及運送。

(7) Identification, housing, location, and transfer of animals. (FDA 58.81(b)(12); JP19-2(4))

8.試驗體系之觀察及調查。

(8) Test system observations. (FDA 58.81(b)(4))

9.瀕死及死亡動物之處理。	(9) Handling of animals found moribund or dead during study. (FDA 58.81(b)(6))
10.實驗動物之活體解剖及死體解剖之檢查。	(10) Necropsy of animals or postmortem examination of animals. (FDA 58.81(b)(7))
11.標本之收集、鑑定及管理。	(11) Collection and identification of specimens. (FDA 58.81(b)(8))
12.組織病理學之檢查。	(12) Histopathology. (FDA 58.81(b)(9))
13.紀錄與報告之管理。	(13) Data handling, storage, and retrieval. (FDA 58.81(b)(10))
14.品質保證工作之執行。	(14) Activity of the quality assurance unit. (JP 19-2(12))
15.試驗安全衛生管制。	(15) Health and safety precautions.
16.廢棄物處理	(16) Handling and disposal of wastes. (NLFD)
17.其他有關事項之管制。	(17) Regulations about other relative items. (NLFD)
二、生物試驗體系	**5.2 Biological test system**
(一)進口、購買、飼(培)養或使用動物、植物、微生物及細胞等，應依據國家有關之法令規定辦理。	1.Proper conditions should comply with appropriate national regulatory requirements for import, collection, care and use of animals, plants, microbial as well as other cellular and sub-celllular systems.

(二)動物、植物、微生物及細胞之購買、飼(培)養及使用應具有標準操作程序，並保存其紀錄以供追溯瞭解其使用歷程。	2.There shall be established standard operating procedures and maintained for the housing, handling and care of animals, plants, microbial as well as other cellular and sub-cellular system, in order to ensure the quality of the data. (OECD 5.2-1)
(三)新購進之動物、植物等在未評估其健康狀態前應予隔離檢疫，若觀察期間有異常疾病或死亡時，該批動物、植物等不得供試驗使用，並予適當處置。	3.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. (OECD5.2-2)
(四)動物、植物、微生物及細胞等於試驗前，應經適當之適應期後始得供試驗。	4.Animal, plant, microbial, and cellular test systems should be acclimatised to the test environment for an adequate period before a study is the first administration/application of the test or control article. (OECD 5.2(5))
(五)在試驗開始時，動物不應有干擾試驗之任何疾病或不良健康狀況發生，若於試驗中有上述情形發生，則該動物應予隔離，必要時對已感染疾病或有疾病徵兆之動物應予治療，而此治療不得對試驗有任何干擾，診療過程及日期均應予記錄保存。	5.At the initiation of a study, animals shall be free of any disease or condition that might interfere with the purpose or conduct of the study. If, during the course of the study, the animals contract such a disease or condition, the diseased animals shall be isolated, if necessary. These animals may be treated for disease or signs of disease provided that such treatment does not interfere with the study. The diagnosis authorizations of treatment, description of treatment and each date of treatment shall be documented and shall be retained. (FDA 58.90(c))

(六)試驗過程必須長期處理或觀察，或因各種原因必須從籠中取出或送回之溫血動物(未斷乳之嚙齒類動物除外)，應有明確之識別方法。每一動物飼養容器外應有明顯之標識，以確認容器內每一試驗動物。	6.Warm-blooded animals, excluding sucking rodents, used in laboratory procedures that require manipulations and observations over and extended period of time or in studies that require the animals to be removed from and returned to their home cages for any reason shall receive appropriate identification. All information needed to specifically identify each animal within an animal- housing unit shall appear on the outside of the unit. (FDA 58.90(d))
(七)不同品種(系)的動物必要時應分別飼養於個別的場所，而相同品種(系)用於不同試驗的動物，若可能因不慎暴露於試驗物質、對照物質或其混合物而影響試驗結果時，原則上不可置於同一室，若必須置於同一室者，則應有適當空間之隔離及明確標示。	7.Animals of different species shall be housed in separate rooms when necessary. Animals of the same species, but used in different studies should not ordinarily be housed in the same room when inadvertent exposure to control or test articles or animal mixup could affect the outcome of either study. If such mixed housing is necessary, adequate differentiation by space and identification shall be made. (FDA 58.90(e))
(八)動物飼養場所、動物籠、架及其他附屬器皿、裝置等應定期清洗與衛生處理。	8.Animals cages, racks and accessory equipment shall be cleaned and sanitized at appropriate intervals. (FDA 58.90(f))
(九)動物籠或盤內所使用之床敷、墊料應不得干擾試驗目的或試驗進行，且應視需要予以更換，以保證動物置於乾燥和清潔之環境。	9.Bedding used in animal cages or pens shall not interfere with the purpose or conduct of the study and shall be changed as often as necessary to keep the animals dry and clean. (FDA 58.90(h))
(十)動物飲水及飼料應定期分析，以確定對試驗產生可能干擾之污染物無超過試驗計畫書內規定的容許範圍，其結果應以原始數據之方式保存。	10.Feed and water used for the animals shall be analyzed periodically to ensure that contaminants known to be capable of interfering with the study and reasonably expected to be present in such feed or water are not present at levels above those specified in the protocol. Documentation of such analyses shall be maintained as raw data. (FDA 58.90(g))

(十一)使用殺蟲劑時應予記錄，若清潔劑及殺蟲劑會干擾試驗時則不可使用。

11.If any pest control materials are used, the use shall be documented. Cleaning and pest control materials that interfere with the study shall not be used. (FDA 58.90(i))

三、試藥與溶液之管制

試驗中使用之試藥與溶液應標示其內容物、濃度、儲存條件、配製日期及有效期限(或再驗日期)。未標示有效期限且性質不安定之試藥與溶液如經長期儲存應予重行檢驗。變質或超過有效期限者不得使用。

5.3 Reagents and solutions

All reagents and solutions in the laboratory area shall be labeled to indicate identity, titer or concentration, storage requirements and expiration date, and as needed, analsized periodically. Deteriorated or outdated reagents and solutions shall not be used. (FDA 58.83)

第陸章　試驗物質及對照物質

Chapter 6 Test and Control Articles

一、試驗物質與對照物質之特性

6.1 Test and control characterization

(一)試驗開始前應確定每批試驗物質或對照物質之本質、力價、純度、組成或其他可以確切顯示該等物質之特性，並予以記錄。試驗機構或試驗委託者應記錄試驗物質及對照物質之合成、製造方法或來源。若以市售商品為對照物質，其特性可用其確定之標誌代替。

1.The identity, strength, purity, and composition or other characteristics which will appropriately define the test or control article shall be determined for each batch and shall be documented. Methods of systhesis, fabrication, or derivation of the test and control articles shall be documented by the sponsor or the testing facility. In those cases where marketed products are used as control articles, such as products will be characterized by their labeling. (FDA 58.105(a))

(二)試驗機構或試驗委託者在開始進行各項試驗前，應確定試驗物質或對照物質之安定性；或依據既定之標準操作程序定期檢驗之。

2. The stability of each test or control article shall be determined by the testing facility or by the sponsor either: before study initiation or concomitantly according to written standard operating procedures, which provide for periodic analysis of each batch. (FDA 58.105(b))

(三)試驗物質及對照物質之每一貯存容器均標示其名稱、編號(代碼)、批號及有效期限，必要時應標示儲存條件。試驗過程中特定試驗物質應置於適當容器貯存之。

3.Each storage container for a test or control articles shall be labeled by name, chemical abstract number or code number, batch number, expiration date, if any, and where appropriate, storage conditions necessary to maintain the identity, strength, purity, and composition of the test or control articles. Storage containers shall be assigned to a particular test articles for the duration of the study. (FDA 58.105(c))

(四)試驗物質之留樣

1.試驗物質與對照物質每一批均應留存具代表性之儲備樣品，其存放條件應與標示者相同。

4. Retention of test articles

(1) A testing facility shall retain reserve samples from each lot of test and control article, under storage conditions by their labeling. (NLFD)

2.儲備樣品之保存期限至少應予留存至試驗結束；當試驗期間超過四週時，向中央衛生主管機關申請藥品查驗登記者，其儲備樣品保存至核准上市後至少二年；其未申請者亦應保存至試驗完成或終止後至少二年。於儲存過程中易腐壞或不安定者應保存至該物質之品質可評估之最後期限。

(2) Each batch of reserve samples should be retained at least until the end of the study. For studies of more than 4 weeks' duration, reserve samples from each batch test and control articles shall be retained for the whichever of the following periods: (i) A period of at least 2 years following the date on which an application for a marketing permit, is approved by the national authority, (ii) Where the study does not result in the submission of the study in support of an application for marketing permit, a period of at least 2 years following the date on which the study is completed, terminated, or discontinued. However, reserve samples of test and control article which show marked changes in quality shall be retained for as long as the quality of the article allows evaluation. (FDA 58.105(d);JP 22-4)

二、試驗物質與對照物質之管制

應制訂試驗物質及對照物質之管制作業程序, 並確保下列各事項：

(一)適當之儲存。

(二)處理及輸送過程具有適當之標識，且確保未受任何污染、變質或損毀。

(三)具有驗收、取樣、儲存及處理之標準操作程序及紀錄，此紀錄應含品名、數量、日期及處理狀況。

三、試驗物質、對照物質與賦形體之混合

(一)每批試驗物質、對照物質與賦形體之混合，應以適當方法分析下述各項：

1.確定試驗物質或對照物質與賦形體混合物之均一性，並定期測試混合物中試驗物質或對照物質之濃度。

2.依據試驗條件，在開始進行各項試驗前，應確定在賦形體混合物中試驗物質或對照物質之安定性；或遵照既定之標準操作程序定期檢驗之。

(二)試驗物質或對照物質之賦形體混合物中有一成分具有效期限，則應加以標示該期限，若不只一成分具有效期限者，應以其最早失效日期標示之。

6.2 Test and control article handling

Procedures shall be established a system for the handling of the test and control articles to ensure that:

1. There is proper storage. (FDA 58.107(a))

2.Proper identification is maintained throughtout the distribution process. Distribution is made in a manner designed to preclude the possibility of contamination, deterioration, or damage. (FDA 58.107(b,c))

3.The receipt and distribution of each batch is documented. Such documentation shall include the date and quantity of each batch distributed or returned. (FDA58.107(d))

6.3 Mixtures of articles with carriers

1.For each test or control article that is mixed with a carrier, tests by appropriate analytical methods shall be conducted:

(1) To determine the uniformity of the the mixture and to determine, periodically, the concentration of the test or control article in the mixture.

(2) To determine the stability of the test and control articles in the mixture as required by the conditions of the study either: (i) Before the study initiation, or (ii) Concomitantly according to written standard operating procedures which provide for periodic analysis of the test and control articles in the mixture. (FDA 58.113(a))

2.Where any of the components of the test or control article carrier mixture has an expiration date, that date shall be clearly shown on the container. If more than one components has an expiration date, the earliest date shall be shown. (FDA 58.113(c))

第柒章　試驗計畫書及試驗之執行

一、試驗計畫書

(一)各項試驗應於試驗前撰寫明確顯示試驗目的及方法之試驗計畫書，並經試驗機構負責人(含試驗委託者)核准及保存之。上述試驗計畫書需記載下列有關事項：

1.試驗名稱、性質及目的。

2.執行試驗之試驗機構及試驗委託者之名稱及住址。

3.試驗主持人姓名。

4.試驗所需人力。

5.試驗開始及結束預定日與預定進度。

6.對照物質及試驗物質應有足以識別之名稱、編 號或代碼。

7.試驗設計之敘述，包括取樣計畫及偏差管制的方法。

Chapter 7 Protocol for and Conduct of a Study

7.1 Protocol

1.Each study shall have an approved written protocol that clearly indicates the objectives and all methods prior initiation of the study. A protocol shall be approved by the management (including the sponsor for studies conducted under contract) which contains the following information in principle. (FDA 58.120(a);JP 25-1)

(1) A descriptive title and statement which reveals the nature and purpose of the study. (FDA 58.120(a)(1);JP 25-1(1);OECD 8.2-1(a)(b))

(2) The name of the sponsor and the name and address of the testing facility at which the study is being conducted (FDA 58.120(a)(3);JP 25-2(2))

(3) The name of the study director. (JP 25-1(3))

(4) Manpower needed for the study. (NLFD)

(5) The proposed experimental starting and completion dates. (OECD 8.2-3(b))

(6) Identification of the test and control articles by name, chemical abstract number or code number. (FDA 58.120(a)(2))

(7) A description of the experimental design, including the methods for the control of bias. (FDA 58.120(a)(6))

8.試驗方法(含執行試驗之調查、分析、測定及觀察之種類與頻率)。	(8) The type and frequency of tests, analyses, and measurements to be made. (FDA 58.120(a)(9))
	(9) Reason for selection of the test system. (JP 25-1(5))
10.試驗體系之特性描述, 例如生物之名稱、數量、體重範圍、年齡、性別、供應來源、品種、品系及其他有關資料。	(10) The number, body weight range, sex, source of supply, species, strain, substrain, and age of the test system. (FDA 58.120(a)(4))
11.試驗體系之識別法。	(11) The procedures for identification of the test system. (FDA 58.120(a)(5))
12.用於動物試驗過程中之溶劑、乳化劑、飼料、飲水等之敘述或鑑別。若已知上述物質中含有影響試驗結果之污染物質, 則須明定該污染物質之容許範圍。	(12) A description and/or identification of the diet used in the study as well as solvents, emulsifiers and/or other materials used to solubilize or suspend the test or control articles before mixing with the carrier. The description shall include specifications for acceptable levels of contaminants that are responsibly expected to be present in the dietary materials and are known to be capable of interfering with the purpose or conduct of the study if present at levels greater than established by the specifications. (FDA 58.120(a)(7))
13.投予途徑及選擇該途徑之理由。	(13) The route of administration of the test and control articles, and the reason for its choice. (JP25(1)(12))
14.投予劑量、方法及頻率。	(14) Each dosage levels of the test or control article to be administered, and the method and frequency of administration. (FDA 58.120(a)(8);JP 25-1(13))

15.統計方法之敘述。	(15) A statement of the proposed statistical methods to be used. (FDA 58.120(a)(12))
16.試驗機構負責人(含試驗委託者)之認可日期與試驗主持人之簽名及簽註日期。	(16) The date of approval of the protocol by the management (including the sponsor for studies conducted under contract) and the dated signature of the study director. (FDA 58.120(a)(11);JP 25-1(17))
17.需保存紀錄與資料之項目。	(17) The records and data to be maintained. (FDA 58.120(a)(10);JP 25-1(16))
(二)經核准之計畫書需作任何修訂或變更時，均應經試驗主持人核准簽名及簽註日期，且需註明其修訂原因並與試驗計畫書共同保存之。	2.All changes in or the revisions of an approved protocol and the reasons thereof shall be documented, signed by the study director, dated, and maintained with the protocol. (FDA 58.120(b))
二、試驗之執行	**7.2 Conduct of a study**
(一)任何試驗均應依據試驗計畫書及有關之標準操作程序執行，並予以追蹤管制。	1.The study shall be conducted in accordance with the protocol and standard operating procedures and monitored in conformity with the protocol. (FDA 58.130(a)(b);JP 26-1)
(二)每一試驗均應有一明確的標示，試驗過程中所使用試藥、溶液及標本等應予明確之標示。	2.Each study shall have a unique identification. The records, reagents, solutions and specimens pertaining to the study shall be accompanied by such identification. (JP 26-2)
(三)標本應以適當方法標示試驗種類、試驗體系之編號及採集日期。	3.The specimens shall be accompanied, using an appropriate method, by the nature of the study, identification number of the test system and date of collection. (FDA 58.130(c);JP 26-3)

(四)解剖取得標本之肉眼觀察結果應予以記錄，以便執行組織病理學檢查之人員參考。

4. Records of gross findings for a specimen from postmortem observation should be available to a pathologist when examining that specimen histopathologically. (FDA 58.130(d))

(五)試驗所得到數據之記錄及變更，應遵循下列各事 項：

5.All data generated during the conduct of a study shall be recorded and recised according to the requirements specified under the following items.

1.試驗過程中產生之數據，均應以不可塗銷之方法直接、迅速、清晰、正確地予以記錄，並簽名及簽註日期。

(1) All data generated during the conduct of a study, except those that are generated by automated data collection system, shall be recorded directly, promptly, and legibly in ink. All data entires shall be dated on the date of entry and signed or initialed by the person entering the data. (FDA 58.130(e);JP 26-5(1))

2.自動數據收集系統產生之數據，於輸入時應由負責鍵入者予以確認簽名及簽註日期。

(2) In automated data collection systems, the individual responsible for direct data input shall be identified at the time of data input. (FDA 58.130(e))

3.任何資料、數據於變更時亦應保留其原始數據，且註明變更原因、日期及確認者簽名。自動數據收集系統產生之數據，鍵入不清楚需變更時，應註明變更原因及鍵入者予以確認簽名及簽注日期。

(3) Any changes in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change, and shall be dated and signed or identified at the time of the change. Any change in automated data entries shall be made so as not to obscure the original entry, shall indicate the reason for change, and shall be dated, and the responsible individual shall be identified. (FDA 58.130(e))

(六)試驗進行中有任何異常或非預期之現象時，參與試驗人員應迅速向試驗主持人報告並詳細記錄之。

6.Personnel engaged in a study shall report promptly any abnormal or unanticipated phenomena which occurred during the course of a study to the study director and shall document the details. (JP 26-6)

第捌章　紀錄與報告

一、總結試驗報告

(一)每一試驗終了時均應依試驗計畫書撰寫總結試驗報告，內容至少需包括下列事項：

1.試驗名稱、性質及目的。

2.試驗機構單位名稱及地址。

3.試驗之開始及完成日期。

4.試驗方法之依據(含執行試驗之調查、分析、測定及觀察之種類與頻率)。

5.取樣及試驗過程中所產生數據之完整紀錄，包括儀器輸出之原始資料及圖譜等。

6.對照及試驗物質之名稱、編號或代碼、批號、力價、純度及組成或其他適當之特性描述以確認該等物質。

Chapter 8 Reports and Records

8.1 Final report

1.A final report shall be prepared for each study and shall include The description specified under the following items in principle. (FDA 58.185(a);JP 27)

(1) A descriptive title and statement which reveals the nature and purpose of the study. (FDA 58.185(a)(2);JP 27-1(1); OECD9.2-1(a))

(2) The name and address of the testing facility. (FDA 58.185(a)(1);JP 27-1(2))

(3) The dates of initiation and completion of the study. (FDA 58.185(a)(1);JP 27-1(3))

(4) A description of the methods used (including the type, frequency and methods of observations, measurements, tests and analyses performed). (FDA 58.185(a)(6);JP 27-1(10))

(5) A complete record of the data generated during sampling and test, including the original data generated by automated equipment. (NLFD)

(6) The test and control articles identified by name, chemical abstracts number or code number, strength, purity, and composition or other appropriate characteristics. (FDA 58.185(a)(4))

7.試驗物質及對照物質於既定之投予條件下之安 定性。	(7) Stability of the test and control articles under the conditions of administration. (FDA 58.185(a)(5))
8.試驗體系之特性描述, 例如生物之名稱、數量、性別、體重範圍、供應來源、品種、品系與其他有關資料及其識別程序。	(8) A description of the test system used,. Where applicable, the final report shall include the number of animals used, sex, body weight range, source of supply, species, strain and substrain, age, and procedure used for identification. (FDA 58.185(a)(7))
9.投予劑量、途徑、頻率及投予期間之記載。	(9) A description of the dosage, dosage regimen, route of administration, and duration. (FDA 58.185(a)(8))
10.試驗主持人及參與試驗人員姓名與業務分配。	(10) The name and job assignment of the study director and all other scientists engaged in the study. (FDA 58.185(a)(10);JP 27-1(11))
11.分析數據所用之統計方法及演算公式。	(11) Statistical methods employed for analyzing the data. (FDA 58.185(a)(3))
12.可能影響數據品質及試驗完整性之因素。	(12) A description of all circumstances that may have affected the quality or integrity of the data. (FDA 58.185(a)(9))
13.試驗數據之運算, 分析及其導出之結論及試驗結果之評估判定與摘要(包括參與試驗人員個別報告之簽名及簽註日期)。	(13) A description of the transformations, calculations, or operation performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis. The signed and dated reports of each of the individual scientists or other professionals involved in the study. (FDA 58.185(a)(11),(12))

14.標本、原始數據及總結試驗報告之儲存場所及期限。

(14) The locations where all specimens, raw data, and the final report are to be stored. (FDA 58.185(a)(13))

15.原始試驗計畫書之任何變更事項。

(15) Objectives and procedures stated in the approved protocol, including any changes in the original protocol. (FDA 58.185(a)(2))

16.品質保證單位依本規範第二章規定作成之報告。

(16) The statement prepared and signed by the quality assurance unit as described in Chapter 2. (FDA 58.185(a)(14))

(二)具結確認數據之真實性及試驗程序均依本規範規定執行，並於總結試驗報告應經試驗主持人簽名。

2. A statement confirming that the study was conducted in accordance with this Standard. The final report shall be signed (or sealed) by the study director. (FDA 58.185(b);UK 43(m))

(三)總結試驗報告之補充或修正應由試驗主持人依一定程序修訂之，且於該報告中清楚顯示其為增補或修正部份，且載明其理由，並由修訂者簽名及簽註日期並由試驗主持人確認之。

3.When there are corrections or additions to the final report, the responsible individual who is involved in such corrections or additions shall clearly indicate the part added or corrected and the date and reasons thereof. Such corrections or additions shall be validated by the study director. (FDA 58.185(c);JP 27-3)

二、紀錄及報告之儲存與追溯

8.2 Storage and retrieval of records and data

(一)試驗產生之所有原始數據、標本(致突變性試驗及血液、尿糞、生物體液得到之標本除外)、紀錄文書、試驗計畫書和總結試驗報告應建檔並予保存。

1.All raw data, documentation, protocols, final report, and specimens (except those specimens obtained from mutagenicty tests and wet specimens of blood, urine, feces, and biological fluids) generated as a result of a study shall be retained in archives. (FDA 58.190(a))

(二)所有原始數據、標本、紀錄文書、試驗計畫書、中間及總結試驗報告均應依序存檔且利於追溯。其儲存狀況應以避免變質為原則，且保存場所應有降低至最小損害之設計；試驗機構亦可委託檔案保管機構提供其適當保存場所。若標本或原始數據與總結試驗報告分開建檔保存時，總結試驗報告之檔案應予詳確記錄。	2.There shall be archives for orderly storage and expedient retrieval of all raw data, documentation, protocols, specimens, and interim and final reports. Conditions of storage shall minimize deterioration of the documents or specimens in accordance with the requirements for the time period of their retention and the nature of the documents or specimens. A testing facility may contract with commercial archives to provide a repository for all material to be retained. Raw data and specimens may be retained elsewhere provided that the archives have specific reference to those other locations. (FDA 58.190(b))
(三)紀錄及報告之儲存場所應有特定人員負責管理且非經授權不可進入。進出檔案室之物品應予記錄。	3.An individual shall be identified as responsible for the archives and only authorized personnel shall enter archives. Movement of materials in and out of the archives should be properly recorded. (FDA 58.190(c)(d);OECD 10. 3)
(四)因試驗規定必須儲存之物質及其有關資料應依序編索以利追溯，例如試驗名稱、試驗物質、試驗日期、試驗體系及試驗本質等之索引。	4.Protocols, specimens, raw data, documentation records and final reports shall be kept in order for expedient retrieval with, for instance, indexing by test article, test system and nature of the study. (FDA 58.190(e);JP 28-5)

三、紀錄及報告之保存期限

(一)試驗產生之所有原始數據、標本(致突變性試驗及血液、尿糞、生物體液得到之標本除外)、紀錄文書、標準操作程序及其制訂歷程、主計畫進度表、試驗計畫書和總結試驗報告等，向中央衛生管機關申請藥品查驗登記者，保存至核准上市後至少五年；其未申請者亦應保存至試驗完成或終止後至少二年。

8.3 Retention period of records and reports

1.Retention of protocols, specimens, raw data, documentation records and final reports required to be retained shall be retained in the archives for the whichever of the following period: (i) A period of at least 5 years following the date on which an application for a marketing permit, is approved by the national authority, (ii) Where the study does not result in the submission of the study in support of an application for marketing permit, a period of at least 2 years following the date on which the study is completed, terminated, or discontinued. (FDA 58.195(b);JP 29-1)

(二)除前款規定外，溼性標本(致突變性試驗及血液、尿糞、生物體液得到之標本除外)，試驗物質或對照物質樣品及經特別處理之物質，保存過程易顯著變質者，應保存至該物質可評估之最後期限。

2. Wet specimens (except those specimens obtained from mutagenicity tests and wet specimens of blood, urine, feces, and biological fluids), samples of test or control articles, and specially prepared material which are relatively fragile and differ markedly in stability and quality during storage, shall be retained only as long as the quality of the preparation affords evaluation. (FDA 58.195(c))

(三)品質保證單位之主計畫進度表、稽查紀錄及負責稽查之試驗計畫書影本均應依序歸檔，並依本章第三項第一款之規定保存於品質保證單位。

3. The master schedule sheet , copies of protocols, and records of quality assurance inspections shall be maintained by the quality assurance unit as an easily accessible system of records for the period of time specified in section 8.3 paragraph 1 of this chapter. (FDA 58.195(d))

(四)所使用儀器之檢查、保養及校正紀錄，應依本章第三項第一款之規定保存。

4. Records and reports of the maintenance and calibration and inspection of equipment shall be retained for the length of time specified in section 8.3 paragraph 1 of this chapter. (FDA58.195(f))

(五)依據本規範第二章之規定有關參與試驗人員之職責、訓練過程及學經歷背景等資料應依本章第三項第一款之規定保存。	5. Summaries of training and experience and job descriptions required to be maintained by chapter 2 may be retained along with other testing facility employment records for the length of time specified in section 8.3 paragraph 1 of this chapter. (FDA58.195(e))
(六)本項之紀錄文書得以原始紀錄文書、相片、顯微影片、電子紀錄或其他精確產生之原始紀錄文書之真實複印本保存之。	6. Records required by this section may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records. (FDA58.195(g))
(七)若試驗機構或委託檔案保管機構結束營運時，本項所述之所有原始數據、紀錄文書、及相關資料檔案應轉移繼任試驗機構；若無法定繼任者時，則轉移試驗委託者指定之檔案室。	7. If a testing facility or an archive contracting facility goes out of business, all raw data, documentation, and other material specified in this section shall be transferred to the legal successor or archives of the sponsor of the study. (FDA 58.195(h);OECD 10.2-3)