電腦化系統確效自我查核表

草案第二版

93.12.20.修正

規 定 內 容	原　　文	自我評審			發現缺失及建議改進事項	備註
		是	不全	否		
一、品質計畫及確效方法	**一、Quality Program and Validation Approach**					
1.公司電腦軟體是否有品質管理計畫及確效的方法？	1.What is the company's approach to software quality and validation?					
二、系統清單	**二、System Inventory**					
1.是否具使用在 GxP*及 Non-GxP 環境分類之系統清單？	1.Is there a system Inventory, categorized by use in GxP and Non-GxP environments?					
2.在 GxP 環境下操作之所有系統是否經確效過？	2.Are all systems operating in a GxP environment validated?					
3.未經確效的系統是否有其行動計畫？	3.Is there an action plan for nonvalidated systems?					
三、內部開發軟體	**三、For Software Developed in House**					
1.是否有開發及測試之文件化程序？其是否足夠及被遵循？	1.Do documented procedures for development and testing exist? Are they adequate and are they followed?					
2.是否有確效計畫書？內容是否合適以及確效是否依據計畫書執行？	2.Is there a validation protocol? Is the content appropriate, and was the validation performed in accordance with the protocol?					
3.是否備有使用者需求規格及功能規格？	3.Are user requirement and functional specifications available?					
4.是否有系統設計規格？	4.Do system design specifications exist?					
5.是否有模組/功能設計規格？	5.Do module/functional design specifications exist?					
6.設計是否經過同意及確認？	6.Has the design been verified by peers?					
7.是否有系統的示意圖及描述？	7.Do system schematics and descriptions exist?					

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8.是否有可能與其他系統連結及交互運用之描述?	8.Is there a description of possible interactions and links with other systems?					
9.是否有原始程式碼之列表？	9.Is there a source code listing?					
10.原始程式碼之註解方式是否能為受過與程式設計者相似教育訓練之人員解讀？	10.Is the source code annotated in such a way that a person with a similar education to the programmer can understand it?					
11.是否有模組測試計畫及結果？	11.Are there module test plans and results?					
12.是否有系統測試計畫、合格標準及測試案例？	12.Are there system test plans, acceptance criteria, and test cases?					
13.測試計畫開始測試前是否均經過授權？	13.Were the test plans authorized before testing started?					
14.測試數據組是否代表實際數據？	14.Do test data sets represent realistic data?					
15.測試數據組是否代表“苛酷”及“最差”狀況？	15.Do test data sets represent stress and worst case conditions?					
16.從規格到測試是否有測試追蹤之矩陣？	16.Is there a test traceability matrix from specifications to testing?					
17.是否有使用者回饋及變更管制之文件化程序？	17.Are there documented procedures for user feedback and change controls?					
18.程式變更歷史檔是否有維護？	18.Are historical files of changes to programs maintained?					
四、向供應商購買之軟體及系統	**四、For Software and Systems Purchased from a Vendor**					
1.是否有購買電腦系統之政策及程序？	1.Is there a policy and procedure for purchasing computerized systems?					
2.是否有確效計畫書？內容是否合適以及確效是否依據計畫書來執行？	2.Is there a validation protocol? Is the content appropriate, and was the validation performed in					

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	accordance with the protocol?					
3.是否備有使用者需求規格及功能規格？	3.Are user requirement and functional specifications available?					
4.是否確認軟體/系統是在合於品質環境下所開發？	4.How did you make sure that the software/system was developed in a quality environment?					
5.供應商是否已建立及維護品質系統？	5.Does the vendor have an established and maintained quality system?					
6.是否所有軟體皆為內部開發？	6.Is all software developed in house?					
7.如果非所有軟體皆為內部開發，轉包商是否依循相同規範？	7.If not all software is developed in house, does the subcontractor follow the same practices?					
8.供應商是否提供確效證據？	8.Does the vendor provide evidence of validation?					
9.可否取得確效文件？	9.Can validation documents be made available?					
10.原始程式碼是否可自供應商處取得？	10.Can the source code be made available at the vendor's site?					
11.是否有軟體/系統追蹤及反應系統，作為缺失報告及增強(升級擴充)需求之用？	11.Is there a software/system tracking and response system for defect reports and enhancement requests?					
12.是否有軟體或電腦系統及預期使用之功能描述？	12.Is there a description of the functions of the software or computer system and its intended use?					
五、測試及操作	**五、Testing and Operation**					
1.是否具測試案例、合格標準及測試結果之合格測試計畫書？	1.Is there a protocol of acceptance testing with test cases, acceptance criteria, and test results?					
2.測試案例是否可追蹤至使用者需求規格及功能規格？	2.Are test cases traceable to functional and user requirement specifications?					

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3.測試數據組是否代表實際數據？	3.Do test data sets represent realistic data?					
4.測試數據組是否代表“最差狀況”？	4.Do test data sets represent worst case conditions?					
5.是否有選項以手工再計算？	5.Have there been manual recalculations of selected jobs?					
6. 是否排定預防維護時程？	6.Is there a preventive maintenance schedule?					
7.是否排定持續性校正時程？	7.Is there a schedule for ongoing calibrations?					
8.是否有系統校正及維護紀錄？	8.Are there records of system calibration and maintenance?					
六、數據/原始數據	**六、Data/Raw Data**					
1.是否有定義、收集、輸入、確認、變更及存檔(原始)數據之標準作業程序？	1.Is there an SOP for defining, collecting, entering, verifying, changing, and archiving (raw) data?					
2.以手工輸入關鍵數據(GxP 數據)，是否經第二者或經確效之電子方法確認？	2.Are critical data (GxP data) entered manually verified by 2nd person, or by a validated electronic method?					
七、文件	**七、Documentation**					
1.現有文件製作(標準作業程序、手冊、設備設計圖、系統設計圖、技術支援文件、規格、認證、線上求助及測試等文件)是否適當且為最新版本？	1.Is existing documentation (Standard Operating Procedures (SOPs)、Manuals、Equipment Design Drawings、System Design Drawings、Technical Support Documents、Specifications、Certification、On-line help and Test Documents) adequate and up-to-date?					
2.是否有設備使用日誌？	2.Is there an equipment logbook?					
3.是否有確效摘要報告及結論？	3.Are there a summary report and conclusions of the validation?					
八、稽核追蹤	**八、Audit Trail**					

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1.是否有數據輸入及處理之稽核追蹤？	1.Is there an audit trail for data entry and processing?					
2.方法、數據的輸入或變更是否包括輸入者資訊，及如經變更之時間及理由？	2.Do inputs or changes to methods and data include information on who entered them, and if they were changed, when and why?					
3.是否這些變更皆自動被電腦控制？	3.Are these changes automatically controlled by the computer?					
4.電腦稽核追蹤功能是否有經確效？	4.Has the computer's audit trail function been validated?					
九、錯誤處理及紀錄	**九、Error Handling and Recording**					
1."錯誤"是否能被系統自動檢出及記錄？	1.Are errors detected and recorded automatically by the system?					
2.自動偵錯機制是否經確效？	2.Have automated error detection mechanisms been validated?					
3.錯誤矯正是否有文件化程序？	3.Are there documented procedures on error corrections?					
十、變更管制	**十、Change Control**					
1.是否有變更管制之程序？	1.Are there procedures for change controls?					
2.系統及程式之改變是否受嚴謹之變更管制，包括再確效及核准？	2.Did alterations to system and programs subject to rigorous change controls, including re-validation and approvals?					
3.這些管制程序是否包括對系統確效狀態衝擊之評估？	3.Do the control procedures include an assessment of the impact on the system's validation status?					
4.是否有確認系統變更後仍符合其預期之用途？	4.How did you make sure that the system was "suitable for its intended use" after the change?					
十一、操作者驗證	**十一、Operator Qualification**					

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1.操作者及程式設計者是否經足夠之相關職務訓練？	1.Are operators and programmers adequately trained for their job?					
2.操作者及程式設計者是否經 GxP 法規之訓練？	2.Are operators and programmers trained on GxP regulations?					
3.臨時員工是否經相關職務訓練，例如測試及 GxP 法規？	3.Have temporary employees been trained for their job, e.g., for testing, and on GxP regulations?					
4.是否保有訓練紀錄？	4.Are training records kept?					
5.是否有訓練計畫之年度回顧？	5.Is there an annual review of the training plan?					
十二、審查/回顧	**十二、Reviews**					
1.是否有電腦系統查核或稽核之文件化程序？	1.Is there a documented procedure for inspections or audits of computer systems?					
2.是否有已執行年度回顧？	2.Have annual reviews been conducted?					
3.所有計畫書及報告之審查及核准是否有品質單位(QA/QC)之參與？	3.The quality unit (QA/QC) is involved in review and approval of all protocols and reports?					
十三、保全及數據完整性	**十三、Security and Data Integrity**					
1.是否建立足夠的保全以防止非授權存取系統，及防止程式、數據及控制參數之損失或變更？	1.Is adequate security established to prevent unauthorized access to the system and loss or changing of programs, date, or control parameters?					
2.是否有經授權可輸入及矯正數據人員之名單？	2.Is there a list of persons who are authorized to enter and correct data?					
3.保全要點是否經確效？	3.Have security features been validated?					
4.是否有程式及數據備份之文件化程序？	4.Is there a documented procedure for backup of programs and data?					
5.如有需要是否可以取得電子儲存數據之印本？	5.Printed copies of electronically stored data available if needed?					

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6.是否有災變復原之文件化程序？	6.Is there a documented procedure for disaster recovery?					
7.是否有評估環境對電腦系統之影響？	7.Is the computer system evaluated for the influence of environment?					
8.是否瞭解任何環境無線電頻率範圍？是否有保護系統以避免無線電頻率或其他電磁干擾之可能不利影響？	8.Is the extent of any environmental radio frequency known? Are systems protected from the possible adverse effects of radio frequency interference or other electromagnetic interference?					
9.是否有文件化程序以要求例行確認已存檔軟體及數據之保留完整而未受人為處理及/或電磁場之損壞？	9.Is there a documented procedure requiring routine verification that archived software and data remain sound and have not been damaged by physical handling and/or electromagnetic fields?					
10.是否具有檢查所有程式有無病毒之程序？	10.Is there a procedure to check all programs for viruses?					
十四、其他	**十四、Other**					
1.負責人員與電腦技術人員的合作關係是否良好？	1.Do key personnel and computer specialists cooperate closely?					
2.電腦系統在規定之使用處所是否有外部機構提供之層級服務合同或合約？	2.Are service level agreements or contracts in place for services provided by outside agencies for computerized systems at regulated user's sites					

*GxP 泛指與醫藥產業相關之作業規範，如 GMP、GCP、GLP…等。

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中英名詞對照

文件	Documentation
文件化程序	Documented procedure
日誌	Log book
示意圖	Schematic
交互運用	Interaction
列表	Listing
印本	Printed copies
同級	Peers
合格標準	Acceptance criteria
回饋	Feedback
存取	Access
存檔(原始)數據	Archiving(raw) data
收集	Collecting
行動計畫	Action plan
技術支援文件	Technical Support Document
災變回復	Disaster recovery
系統設計圖	System Design Drawing
定義	Defining
保全	Security
保全要點	Security Feature
政策	Policy
查核	Inspection
負責人員	Key personnel
原始程式碼	Source code
矩陣	Matrix
缺失報告	Defect report
執行	Performed
排程	Schedule
人員之名單	List of persons
規格	Specifications
設備設計圖	Equipment Design Drawing
最新版本	Up-to-date
程式設計者	Programmer
損失	Loss
預期使用	Intended use
實體處理	Physical handling
認證	Certification
增強	Enhancement
審查/回顧	Reviews
確效證據	Evidence of validation
確認	Verifying
稽核追蹤	Audit Trail
範圍	Extent
線上求助	Online help
輸入	Entering; Input
儲存	Archived
檢查	Check
矯正數據	Correct data
轉包商	Subcontractor

英中名詞對照

Acceptance criteria	合格標準
Access	存取
Action plan	行動計畫
Archived	儲存
Archiving(raw) data	存檔(原始)數據
Audit Trail	稽核追蹤
Certification	認證
Check	檢查
Collecting	收集
Correct data	矯正數據
Defect report	缺失報告
Defining	定義
Disaster recovery	災變回復
Documentation	文件
Documented procedure	文件化程序
Enhancement	增強
Entering	輸入
Equipment Design Drawing	設備設計圖
Evidence of validation	確效證據
Extent	範圍
Feedback	回饋
Input	輸入
Inspection	查核
Intended use	預期使用
Interaction	交互運用
Key personnel	負責人員
List of persons	人員之名單
Listing	列表
Log book	日誌
Loss	損失
Matrix	矩陣
Online help	線上求助
Peers	同級
Performed	執行
Physical handling	實體處理
Policy	政策
Printed copies	印本
Programmer	程式設計者
Reviews	審查/回顧
Schedule	排程
Schematic	示意圖
Security	保全
Security Feature	保全要點
Source code	原始程式碼
Specifications	規格
Subcontractor	轉包商
System Design Drawing	系統設計圖
Technical Support Document	技術支援文件
Up-to-data	最新版本
Verifying	確認