核對表 **Checklist 2E**

香港中醫藥管理委員會
Chinese Medicine Council of Hong Kong

申請製造商證明書(中成藥生產質量管理規範)文件核對表

Documentation Checklist
Application for Certificate for Manufacturer
(Good manufacturing practice in respect of proprietary Chinese medicines)

請將此文件核對表連同下列文件，與**製造商證明書（中成藥生產質量管理規範）申請表（表格 1E**）一併親身提交或郵寄衞生署中醫藥規管辦公室。假如你對下述第 1 至 12 項，任何一項的答案 是「否」，請附上書面解釋。

Please submit in person or by post this documentation checklist together with the following documents and the **Application Form for Certificate for Manufacturer (Good manufacturing practice in respect of proprietary Chinese medicines) (Form 1E)** to the Chinese Medicine Regulatory Office of the Department of Health. If your answer to any one of the following items 1 to 12 is "No", please attach an explanation in writing.

你是否已經提交 Have you submitted:	是 Yes	否 No
1. 一份填妥的製造商證明書(中成藥生產質量管理規範)申請表 (表格 1E) A duly completed "Application Form for Certificate for Manufacturer (Good manufacturing practice in respect of proprietary Chinese medicines)" (Form 1E)	☐	☐
2. 商業登記證副本 Copy of Business Registration Certificate	☐	☐
3. 中成藥製造商牌照副本 Copy of Manufacturer Licence in proprietary Chinese medicines	☐	☐
4. 製造商的基本資料 Basic information of manufacturer		
a. 製造商的品質管理系統簡述 Brief description of quality management system of manufacturer	☐	☐
b. 公司組織架構圖 (包括各部門的職責及相互關係、部門主管) Organization chart (including responsibilities of departments, relationships between departments, department heads)	☐	☐
c. 所製造或擬製造的產品劑型和品種表 Table of dosage forms and type of products being manufactured or to be manufactured	☐	☐
d. 所經營的製造業務 (包括藥品和非藥品製造業務) Manufacturing business carried out (including medicine and non-medicine manufacturing business)	☐	☐
e. 從事製造、品質控制、物料和產品的貯存和分銷的員工數目 Number of personnel involved in manufacture, quality control, and storage and distribution of materials and products	☐	☐

	是 Yes	否 No
5. 人員資料 Personnel information		
a. 關鍵人員的資歷 (學歷證明及/或有關工作經驗證明) 及其職責 Qualifications (evidence of academic qualifications and/or documentary proofs of relevant working experience) and responsibilities of key personnel	☐	☐
b. 人員訓練計劃 Training program for personnel	☐	☐
c. 個人衞生措施 (健康檢查、工作服裝的要求等) Personal hygiene measures (health examinations, requirements of working clothing, etc.)	☐	☐
6. 廠房和設施資料 Premises and facilities information		
a. 廠房簡述 (地點、平面簡圖、總面積) Brief description of premises (location, brief floor plan, total area)	☐	☐
b. 設施簡述 Brief description of facilities	☐	☐
7. 設備資料 Equipment information		
a. 主要製造設備和品質控制設備的清單 List of major manufacturing equipment and quality control equipment	☐	☐
8. 文件系統簡述 Brief description of documentation system	☐	☐
9. 製造管理資料 Manufacturing management information		
a. 製造流程簡圖，並註明主要製造過程控制點 Simple flow chart of manufacturing processes with indication of major in-process control points	☐	☐
b. 物料和產品處理流程簡圖 (接收、拒收、發放、貯存和棄置的安排) Simple flow chart of materials and products handling (arrangements for receipt, rejection, release, storage and disposal)	☐	☐
10. 品質控制資料 Quality control information		
a. 品質控制系統簡述 Brief description of quality control system	☐	☐
b. 品質控制部門的職責 Responsibilities of quality control department	☐	☐
11. 處理投訴和產品回收資料 Complaint handling and product recall information		
a. 處理有關產品品質的投訴的措施 Measures for handling complaints about product quality	☐	☐
b. 產品回收系統簡述 Brief description of product recall system	☐	☐

	是 Yes	否 No
12. 自檢計劃 Self-inspection program	☐	☐
13. 合約製造和合約檢驗資料 Contract manufacture and test information		
a. 委託其他製造商進行合約製造的資料 (如有) Information on contract manufacturing given out to other manufacturers (if any)	☐	☐
b. 委託其他檢驗機構進行合約檢驗的資料 (如有) Information on contract test given out to test organizations (if any)	☐	☐
c. 接受委託進行合約製造的資料 (如有) Information on contract manufacture accepted (if any)	☐	☐
14. 其他資料（如有）: Other information (if any): _____ _____ _____	☐	☐

註： 如有需要，中藥組可要求申請人提交其他證明文件及上述文件的正本，以供核對。

Note: Where necessary, the Chinese Medicines Board may require the applicant to submit other documentary proofs and the originals of the said documents for verification.