

Deviation Management & Corrective and Preventive Actions

TARGET AUDIENCE

- Members of The Pharmaceutical Distributors Association of Hong Kong (PDAHK)
- Person-in-charge of secondary packaging of licensed manufactures of secondary packaging

COURSE INFORMATION

Course date:	11 July, 2026 (SAT) - M812C/HK-07A
Time:	9:00 am - 1:00 pm (4 hours - half-day course)
Venue:	HKQAA, 19/F., K. Wah Centre, 191 Java Road, North Point
Language:	Cantonese with Traditional Chinese Material
Course fee:	• HK \$2,000 (Public); • HK \$1,600 (PDAHK Member)

^Please click [here](#) to see PDAHK member list.

Continuing Professional Development (CPD) Training Program



4 HOURS

CPD Equivalence



APPROVED

Approved Course Code:
CPD/L/02/2026

Remark: CPD hours would only be awarded one-off on completion of the course and NO CPD hours would be awarded upon repeated attendance within 24 months.

COURSE HIGHLIGHT

Module 1 Introduction

- Regulations and regulatory expectations
- Definition of deviation
- Difference between deviation, nonconformance, and incident
- GMP scope covered by deviation management

Module 2 Deviation Management Process Flow

- Deviation identification and categorization
- Reporting, documentation, and containment
- Classification and root cause analysis
- Impact assessment and CAPA
- CAPA approval, implementation, report completion, record archiving, and closure

Module 3 Setting Up a Deviation System

- SOP, process flow, deviation form, and deviation register
- Common Problems of Handling Deviation
- Tips of Proper Handling of Deviation

Module 4 Preventing Recurrence

- How to Reduce Repeated Deviations or Incidents

CERTIFICATE FOR COMPLETION



Certificate for Completion will be jointly issued by HKQAA and PDAHK to participants who pass the examination (M.C) and participate in 100% attendance of the course.



APPLY HERE

[VISIT OUR WEBSITE](#)



Katie Chan

(852) 2202-9368



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9:00 am - 6:00 pm (Monday to Friday)

偏差管理與糾正預防措施

目標對象

- 香港醫藥經銷業協會 (PDAHK) 會員
- 二次包裝製造商、二次包裝負責人和品質保證主任

課程詳情

課程日期：	2026年7月11日 (六) - M812C/HK-07A
時間：	早上9時正 至 下午1時正 (4小時)
地點：	香港北角渣華道191號嘉華國際中心19樓
語言：	粵語輔以繁體中文教材
課程費用：	- 參加者每位港幣 2,000 (公開價) 參加者每位港幣 1,600 (會員價)

^ 點擊此瀏覽PDAHK會員名單。

持續專業發展課程 (CPD Training Program)



4 小時

CPD有效時數



已獲審批

已批准的課程編號：
CPD/L/02/2026

備註：CPD時數僅在完成此課程後一次性授予，24 個月內重複報讀此課程將不會授予 CPD 時數。

修業證書

參加者須確保 100%出席並通過考試，方能獲得由香港品質保證局及香港醫藥經銷業協會會員聯合頒發「課程修業證書」乙張。

課程內容

簡介

- 法規要求與監管機構之期望
- 偏差 (Deviation) 定義
- 偏差、不符合事項 (Nonconformance) 與事件 (Incident) 之區別
- 偏差管理所涵蓋的 GMP 範圍

單元一

偏差管理流程

- 偏差之識別與類別劃分
- 報告、文件記錄與圍堵措施
- 偏差分類與根本原因分析 (RCA)
- 品質風險管理 (QRM) 影響評估與糾正預防措施 (CAPA)
- CAPA 之核准、實施、報告完成、檔案歸檔與結案

單元二

建立偏差管理系統

- 基礎要素：標準作業程序 (SOP)、流程圖、偏差記錄表、偏差登記簿
- 常見處理問題
- 偏差妥善處理之建議與技巧

單元三

預防重複發生

- 如何降低重複性偏差或事故的發生率

單元四



立即報名

了解更多



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