

EU Pharma GDP 歐盟醫藥良好分銷規範

Standard Understanding Training 標準理解培訓 (#GDP-EU-U2R)

Internal Auditor Training 內審員培訓 (#GDP-EU-IA2)

Training Objectives 培訓目標

- To understand the basics of EU Guidelines on Good Distribution Practice for pharmaceutical products for human use (EU GDP)
瞭解歐盟的人用藥物的良好分銷規範的概況
- To understand the principles of quality management in EU GDP
瞭解歐盟良好分銷規範中的質量管理原則
- To understand the requirements for logistics in EU GDP
瞭解歐盟於良好分銷規範中對物流的要求
- To develop the basic expertise to implement a QMS according to EU GDP
發展依據歐盟良好分銷規範實施質量管理體系所需基礎技能
- To develop the basic expertise for internal audits (for Internal Auditor Course)
發展進行內部審核所需基礎技能 (適用於內審員課程)

Note 注:

The interpretation of the regulations is just for the purpose of quality management system. Please consult lawyers before making decisions related to regulations.

對法規要求的闡釋只限用於質量管理體系的目的。在做出與法規相關的決策前請先諮詢律師意見。

Recommended Prior Knowledge 建議的事先認知

- Experience in pharmaceutical logistics or distribution
醫藥物流或分銷經驗
- Problems in pharma logistics or distribution operations
在醫藥物流或分銷中遇到的問題



Suitable for 培訓對象

- Auditors, Managers, Engineers, Experts, Consultants in pharmaceutical related field.
與醫藥物流或分銷相關領域的審核員、工程師、管理層、專業人仕、顧問
- Persons seeking career opportunities in pharmacy field /Certification Bodies.
尋找與醫藥物流或分銷領域 / 認證機構相關的就業機會的人仕

**Keep learning.
Be outstanding!**



Training Approach 培訓形式

- Lecturing by tutor 講師面授
- Exercises (individual or by team) 練習 (個人或小組)
- Workshops 討論演練
- Language: English or Chinese
語言：英文或中文
- Tutor: Experienced Trainer with Auditor Qualification
講師：經驗豐富的具備審核員資格的培訓師



Course Agenda 課程安排

Day 日程	Items 項目	Evaluation 評估
Part 1	<ul style="list-style-type: none"> • Introduction 介紹 • Quality management 質量管理 • Personnel 人事 • Premises and equipment 設施和設備 • Documentation 文件 • Operations 運作 • Complaints, returns, suspected falsified medical products and medicinal product recalls 投訴・退貨・涉嫌偽造醫療產品和藥品召回 	Participation Required 要求參與
Part 2	<ul style="list-style-type: none"> • Outsourced activities 外包活動 • Self-inspection 自我檢查 • Transportation 運輸 • Specific provisions for brokers 經紀人的具體規定 • Final provisions 最後條款 • Q&A 問答 	Participation Required 要求參與
	• Written Exam 筆試 <open book 開卷> (1 hr 小時)	Pass: >=60%



Course No.課程編號	Lecturing 授課	Remark 備註
#GDP-EU-U1	1.5 days 天	
#GDP-EU-IA2R	2 days 天	Add Internal Audit Module 增加內審模塊

Evaluation and Certificate 評估和證書

1. Evaluation based on Participation 參與表現評估

- A Certificate of Attendance by DQS will be issued to the registered participants who have participated in the whole training course and completed all assignments, but have not been successful in passing the exam.

全程出席並完成課程任務，但未能通過考試的學員可獲得DQS頒發的培訓出席證書。

2. General Evaluation 綜合評估

- A Certificate of Successful Completion by DQS will be awarded to registered participants who have participated in the whole training course, completed all assignments, and passed the exam.

全程出席和完成課程任務，並通過考試的註冊學員可獲得DQS頒發的培訓完成證書。



Contact Information 聯絡信息

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