ISO 13485:2016

Foundation Training 基礎培訓 (#MD-F1)

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

Internal Auditor Training 內部審核員培訓 (#MD-IA2)

Training Objectives 培訓目標

- To understand the development of and primary changes to ISO 13485:2016

  瞭解 ISO 13485:2016 的發展及其主要變更
- To understand ISO 13485:2016 standard requirements

  瞭解 ISO 13485:2016 的標準要求
- To have basic awareness about MDSAP, FDA and CE Approvals

  初步認知醫療器械單一審核方案、FDA 和 CE 審批
- To develop the basic expertise to implement a QMS according to ISO 13485:2016

  發展依據 ISO 13485:2016 實施質量管理體系所需基礎技能
- To develop the basic expertise for internal audits based on ISO 13485:2016

  發展根據 ISO 13485:2016 的標準要求進行內部審核所需基礎技能
- Since ISO 13485:2016 is based on ISO 9001:2008, this training course does NOT automatically cover ISO 9001:2015.

  ISO 13485:2016 是建基於 ISO 9001:2008, 所以本培訓課程並**不**自動包括 ISO9001:2015 的內容。

Recommended Prior Knowledge 建議的事先認知

- Application experience in ISO13485 or ISO9001

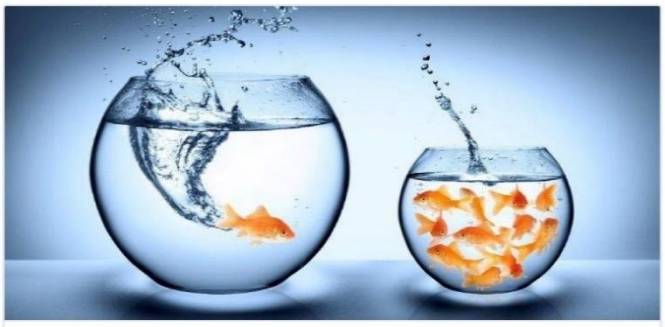
  ISO 13485 或 ISO 9001 應用經驗
- Problems in the implementation of MDQMS in own organization

  本身組織的醫療器械質量管理體系運行中遇到的問題

Suitable for 培訓對象

- MDQMS Auditors, MR, Managers, Engineers, Experts in quality related field.
  醫療設備質量管理體系審核員、工程師、管理層、質量管理領域相關的專業人仕
- Persons seeking career opportunities in QMS field /Certification Bodies.
  尋找與質量管理領域 / 認證機構相關的就業機會的人仕

Keep learning.
Be outstanding!



Training Approach 培訓形式

- Exercises (individual or by team)
  練習 (個人或小組)
- Workshops
  討論演練
- Lecturing and training materials in Chinese, unless otherwise specified
  授課語言和培訓資料爲中文，除非另文規定
- Tutor: Experienced Trainer with QMS Auditor Qualification
  講師： 經驗豐富的具備質量管理體系審核員資格的培訓師

Course Agenda 課程安排 1 - 2 days 天

Day 日程	Items 項目	Evaluation 評估
Part 1	• General introduction to ISO 13485:2016 簡介 • Key changes to the new standard 新版標準的主要變化點 • Standard Requirements Understanding 標準要求的理解 • Discussions / Exercises 討論 / 練習 • Q&A 問答 (Above for Foundation Course 以上為基礎培訓的內容)	Participation Required 要求參與
Part 2	• Basic Introduction of FDA & CE approvals for Medical Devices 初步介紹醫療器械的 FDA 和 CE 審批 • Basic Introduction of MDSAP 初步介紹醫療器械單一審核方案 • Internal Audit 內審 (for I.A. Course 針對內審員課程) • Workshops 討論演練 • Q&A 問答	Participation Required 要求參與
	• Evaluation 測評	

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 general evaluation.
  全程出席並完成課程任務，但未能通過綜合測評的註冊學員可獲得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 general evaluation.
  全程出席和完成課程任務，並通過綜合測評的註冊學員可獲得DQS頒發的培訓完成證書。

Contact Information 聯絡信息

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Registration Form 報名表