



# ISO 13485:2016 Internal Auditor Training 內部審核員培訓 (#MD-IA2)

(with emphasis on Surgical Mask manufacturing 着重医用口罩制造)

## 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 understand the key requirements associated with surgical mask manufacturing  
瞭解與醫用口罩製造相關的關鍵要求
- 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, Consultants 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、顧問
- 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為中文·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

~ 2 days 天

Day 日程	Items 項目	Evaluation 評估
<b>Part 1</b>	<ul style="list-style-type: none"><li>• General introduction to ISO 13485:2016 簡介</li><li>• Key changes to the new standard 新版標準的主要變化點</li><li>• Standard Requirements Understanding 標準要求的理解</li><li>• Key Requirements associated with Surgical Masks manufacturing 醫用口罩製造相關的關鍵要求 (embed into each section 融入各章節)</li><li>• Workshops 討論演練</li><li>• Q&amp;A 問答</li></ul>	Participation Required 要求參與
<b>Part 2</b>	<ul style="list-style-type: none"><li>• Basic Introduction of FDA &amp; CE approvals for Medical Devices 初步介紹醫療器械的 FDA 和 CE 審批</li><li>• Basic Introduction of MDSAP 初步介紹醫療器械單一審核方案</li><li>• Internal Audit 內審</li><li>• Workshops 討論演練</li><li>• Q&amp;A 問答</li></ul>	Participation Required 要求參與
	<ul style="list-style-type: none"><li>• Evaluation 測評</li></ul>	





## 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](#)