ISO 13485

Medical devices — Quality management systems

To gain the chance to enter local and oversea markets for medical devices and related services, you need to ensure your quality management system meets ISO 13485 requirements. ISO 13485 is applicable to any medical device organization, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). It can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations.

ISO 13485 contains requirements for improvement, using feedback from sources such as complaint handling, post market surveillance, handling of nonconformities, corrective actions and preventive actions. To ensure that worthwhile and cost effective improvements are being achieved.

It is applicable to all types of organizations, whether public or private sector, regardless of the type, size and nature of the organization or geographical location. It is a basis for such organizations to demonstrate her ability to meet customer and applicable regulatory requirements.

Benefits:

- Improve company's credibility and image
- Meet the requirement of laws and regulations of oversea countries and expectation of public, in order to expand the oversea market
- Improve processes & facilitate greater efficiency & cost savings
- Better employee engagement & to prove the products or services are effective & safe
- Improve customer satisfaction

國際認可認証有限公司
Accredited Certification International Limited

www.aci-limited.com

TEL: (852) 3977 8988 FAX: (852) 2806 1940
EMAIL: ENQUIRY@ACI-LIMITED.COM
WEBSITE: WWW.ACI-LIMITED.COM

ISO 13485

醫療器材品質管理系統

為了有機會進入醫療設備和醫療質量控制的海外市場，您需要確保質量管理體系滿足ISO 13485要求。ISO 13485適用於任何醫療器材組織，包括醫療設備的設計和開發，生產，儲存和分配，安裝或服務以及設計和開發或提供相關活動（例如技術支援）。供應商向此類組織提供產品（包括與質量管理系統相關的服務）的各方也可以使用它。

ISO 13485著重要求改進，利用從投訴處理，市場監視，不合格處理，糾正措施和預防措施等來源的反饋。確保實踐其價值且具有成本效益的改進。

它適用於所有類型的組織，無論是公共部門還是私營機構，類型，規模和性質或地理位置，這些組織可以證明自己能滿足客戶的能力和達到法規的要求。

好處:

- ◆提高公司的信譽和形象
- ◆符合海外國家法律法規的要求和公眾的期望，以擴大海外市場
- ◆改善流程並促進更高的效率和成本節省
- ◆更好的員工敬業度，並證明產品或服務有效且安全
- ◆提高客戶滿意度

國際認可認証有限公司
Accredited Certification International Limited

www.aci-limited.com

TEL: (852) 3977 8988 FAX: (852) 2806 1940
EMAIL: ENQUIRY@ACI-LIMITED.COM
WEBSITE: WWW.ACI-LIMITED.COM

ISO 13485

Medical Devices — Quality Management Systems

TMD 1	**ISO 13485 Introduction**	**3 hours**

Details
~ Discuss the needs for and benefits of the ISO 13485
~ Introduce the terms and definitions
~ Familiarize participants with basic concepts
~ Understand the certification process and its necessary requirements

TMD 2	**ISO 13485 Effective Application**	**1 day**

Details
~ Introducing ISO 13485
~ Interpretation on the requirements and implementation of ISO 13485
~ Introduction to Medical Devices — Quality Management Systems
~ Interpretation of all ISO 13485 clauses

TMD 3	**ISO 13845 Documentation**	**1 day**

Details
~ ISO requirements for documentation and why documentation required
~ Process approach to create practical documents
~ System Documentation
~ Updating and Maintenance of ISO 13485 Quality Management Systems

TMD 4	**ISO 113485 Internal Auditor Training**	**2 days**

Details
~ ISO 13485 Documentation review
~ Understand ISO 13485 Quality Management Systems audit model
~ Comparison between internal and external audit
~ Internal auditing (including audit planning, auditing methodology, auditing skills (preparation and monitoring), Internal audit results evaluation and reporting

Date	Courses are organized once a month. Detailed schedule can be found on our website.
Venue	ACI Training Centre
Methodology	Presentation, Workgroup Discussion, Case Study & Exercise
Certificate	Certificate of successful completion will be issued to delegates who have attended full course

國際認可認証有限公司
Accredited Certification International Limited

www.aci-limited.com

TEL: (852) 3977 8988 FAX: (852) 2806 1940
EMAIL: ENQUIRY@ACI-LIMITED.COM
WEBSITE: WWW.ACI-LIMITED.COM

ISO 13485

醫療器材品質管理系統

TMD 1	**ISO 13485 入門**	**3 小時**

培訓內容:
~ 探討為何需要 ISO 13485 及其好處
~ 概述術語和定義
~ 讓學員了解基本概念
~ 了解認証過程及其基本要求

TMD 2	**ISO 13485 有效應用**	**1 日**

培訓內容:
~ 介紹ISO 13485
~ 解釋ISO 13485 的要求與執行
~ 醫療器材品質管理系統介紹
~ 解釋ISO 13485 所有條款

TMD 3	**ISO 13485 文件處理**	**1 日**

培訓內容:
~ ISO 13485 對文件的要求及為何有此要求
~ 過程方法以建立實用文件
~ 系統文件
~ 更新和維護品質管理系統

TMD 4	**ISO 13485 內部審核員培訓**	**2 日**

培訓內容:
~ ISO 13485 文檔記錄概述
~ 了解ISO 13485品質管理系統審核模型
~ 內部審核與外部審核的比較
~ ISO 13485品質管理系統內部審核
(包括審核計劃，審核方法，審核技巧，準備和監督)
~ 內部審核結果評估和報告

上課日期	培訓課程每月舉辦一次，具體開課日期可瀏覽本公司網頁
地點	ACI 培訓中心
上課模式	講解、小組討論、練習及個案研習
獲取資格	完成課程之學員將獲頒發課程完成證書乙張

國際認可認証有限公司
Accredited Certification International Limited

www.aci-limited.com

TEL: (852) 3977 8988 FAX: (852) 2806 1940
EMAIL: ENQUIRY@ACI-LIMITED.COM
WEBSITE: WWW.ACI-LIMITED.COM